Proposed Grant Awards

November 19, 2015

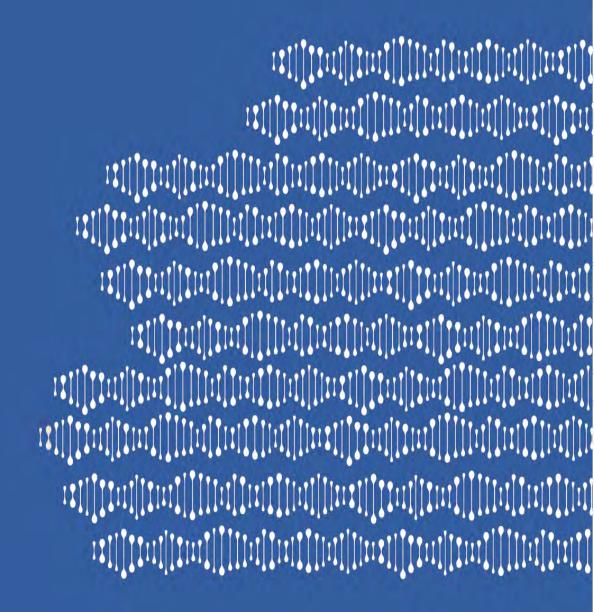


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CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

November 5, 2015

Dear Oversight Committee Members:

I am pleased to present the Program Integration Committee's (PIC) unanimous recommendations for funding 73 grant applications totaling \$112,009,012. The PIC recommendations for 60 academic research grant awards, 1 product development award, and 12 prevention awards are attached.

Dr. Margaret Kripke, CPRIT's Chief Scientific Officer, Mr. Michael Lang, CPRIT's Chief Product Development Officer, and Dr. Becky Garcia, CPRIT's Chief Prevention Officer, have prepared overviews of the academic research, product development, and prevention program slates to assist your evaluation of the recommended awards. The overviews are intended to provide a comprehensive summary with enough detail to understand the substance of the proposal and the reasons endorsing grant funding. In addition to the full overviews, all of the information considered by the Review Councils is available by clicking on the appropriate link in the portal. This information includes the application, peer reviewer critiques, and the CEO affidavit for each proposal.

For the first time the PIC has used the award deferral process set by CPRIT administrative rule § 703.7(d) to defer the decision to recommend awards for two prevention applications until a future FY 2016 meeting. PP160046 and PP160033, totaling \$2,999,657, were recommended by the Prevention Review Council (PRC). The PIC's unanimous decision conserves prevention award funds for the second FY2016 funding cycle. The two deferred applications were ranked the lowest of the prevention grants recommended for funding. After considering proposals submitted in the next cycle, the PRC may recommend funding one or both deferred applications. No Oversight Committee action is necessary at this time.

The approval of these grant recommendations is governed by a statutory process that requires two-thirds of the members present and voting to approve each recommendation. Vince Burgess, CPRIT's Chief Compliance Officer, will certify that the review process for the recommended grants followed CPRIT's award process prior to any Oversight Committee action.

The award recommendations will not be considered final until the Oversight Committee meeting on Thursday, November 19, 2015. Consistent with the non-disclosure agreement that all Oversight Committee members have signed, the recommendations should be kept confidential and not be disclosed to anyone until the award list is publicly announced at the Oversight Committee meeting. I request that Oversight Committee members not print, email or save to your computer's hard drive any material on the portal. I appreciate your assistance in taking all necessary precautions to protect this information.

If you have any questions or would like more information on the review process or any of the projects recommended for an award, CPRIT's staff, including myself, Dr. Kripke, Mr. Lang, and Dr. Garcia are always available. Please feel free to contact us directly should you have any questions. The programs that will be supported by the CPRIT awards are an important step in our efforts to mitigate the effects of cancer in Texas. Thank you for being part of this endeavor.

Sincerely, Wayne R. Roberts Chief Executive Officer

Academic Research Award Recommendations –

The PIC unanimously recommends approval of 60 academic research grant proposals totaling \$78,761,270. The recommended grant proposals were submitted in response to eight grant mechanisms: Individual Investigator Research Awards; Individual Investigator Research Awards for Cancer in Children and Adolescents; Individual Investigator Research Awards for Prevention and Early Detection; Research Training Awards; Recruitment of First-Time, Tenure-Track Faculty; Recruitment of Rising Stars, and Recruitment of Established Investigators. The PIC followed the recommendations made by the Scientific Review Council (SRC). The SRC provided the prioritized list of recommendations for the Recruitment awards to the presiding officers on October 26, 2015. Dr. Kolodner corrected a score for one grant, RP160268, in a letter dated October 29, 2015, which slightly affected the grant's ranking.

The PIC is required to give funding priority, to the extent possible, to applications that meet one or more criteria set forth in V.T.C.A., TEX. HEALTH & SAFETY CODE § 102.251(a)(2)(C). The PIC determined that these academic research proposals met the following CPRIT funding priorities:

- could lead to immediate or long-term medical and scientific breakthroughs in the area of cancer prevention or cures for cancer;
- strengthen and enhance fundamental science in cancer research;
- ensure a comprehensive coordinated approach to cancer research and cancer prevention;
- are interdisciplinary or interinstitutional;
- address federal or other major research sponsors' priorities in emerging scientific or technology fields in the area of cancer prevention or cures for cancer;
- are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;
- are collaborative between any combination of private and nonprofit entities, public or private agencies or institutions in this state, and public or private institutions outside this state (the PIC chose this factor for Multi-Investigator Research Awards and High-Impact, High-Risk Research Awards);
- have a demonstrable economic development benefit to this state;
- enhance research superiority at institutions of higher education in this state by creating new research superiority, attracting existing research superiority from institutions not located in this state and other research entities, or enhancing existing research superiority by attracting from outside this state additional researchers and resources;
- Expedite innovation and commercialization, attract, create, or expand private sector entities that will drive a substantial increase in high-quality jobs, and increase higher education applied science or Technology research capabilities; and
 - This factor only applies to Individual Investigator Research Awards; Individual Investigator Research Awards for Cancer in Children and Adolescents; Individual Investigator Research Awards for Computational Biology; Individual Investigator Research Awards for Prevention and Early Detection; Recruitment of First-Time, Tenure-Track Faculty; Recruitment of Rising Stars, and Recruitment of Established Investigators
- address the goals of the Texas Cancer Plan.

Academic Research Grant Award Recommendations

Rank	App ID	Organization/Company	Application Title	Award Amount	Mech.	Overall Score
		The University of Texas	Cancer Intervention and		RTA-	
1	RP160157	Southwestern Medical Center	Prevention Discoveries Program	\$3,993,250	Renewal	1.2
			Decoding Cellular Heterogeneity			
2	RP160192	Baylor College of Medicine	of Malignant Glioma	\$899,701	IIRA	1.3
			Protein Truncation Mutations in			
3	RP160451	Baylor College of Medicine	WIP1: Effects on Cancer and	\$900,000	IIRA	1.5
	P	The University of Texas	Development of Therapeutics Targeting Truncated Adenomatous Polyposis Coli (APC) as a Novel Prevention and Intervention	***************************************		
4	RP160180	Southwestern Medical Center	Strategy for Colorectal Cancer	\$900,000	IIRA	1.8
5*	RP160237	The University of Texas M. D. Anderson Cancer Center	A novel epigenetic reader as therapeutic target in MLL-translocated pediatric leukemias	\$900,000	IIRACC A	1.8
			Baylor College of Medicine		RTA-	
6	RP160283	Baylor College of Medicine	Comprehensive Cancer Training Program	\$3,986,268	Renewal	1.9
O	KI 100203	The University of Texas	Training Trogram	\$5,760,200	rene war	1.7
		Health Science Center at San			IIRACC A	
7	RP160487	Antonio	Cytokine signaling in Ewing sarcoma	\$1,200,000		1.9
8	RP160030	The University of Texas Southwestern Medical Center	A Randomized Controlled Trial (RCT) of Patient Navigation for Lung Cancer Screening in an Urban Safety-Net System	\$1,492,616	IIRAP	1.9
9	RP160384	Baylor College of Medicine	Promoting The Functions of Memory T cells for Adoptive T cell Therapy	\$887,676	IIRA	1.9
10	RP1	The University of Texas Southwestern Medical Center	Role of Long Non-Coding RNAs in Breast Cancer: Identification, Characterization, and Determination of Molecular Functions Arylhydrocarbon receptor	\$886,652	IIRA	2.0
11	RP160589	Texas AgriLife Research	mediated modulation of colorectal cancer by microbiota	\$890,840	IIRAP	2.0
12**	RP160190	The University of Texas Southwestern Medical Center	Pediatric Radiation Oncology with Movie Induced Sedation Effect (PROMISE)	\$900,000	IIRACC A	2.0
12	RP160497	The University of Texas M. D. Anderson Cancer Center	Amplified gold nanoparticle- mediated radiosensitization of	\$800.200	IID A	2.0
13	KF10049/	Anderson Cancer Center	Imaging-based quantitative analysis	\$899,309	IIRA	2.0
14	RP160229	The University of Texas M. D. Anderson Cancer Center	of vascular perfusion and tissue oxygenation to improve therapy of hepatocellular carcinoma	\$885,901	IIRA	2.0
15	RP160169	The University of Texas Southwestern Medical Center	Molecular Mechanism of NLRP12- mediated Regulation of Colorectal Cancer	\$897,707	IIRA	2.1
16***	RP160249	The University of Texas Southwestern Medical Center	DIS3L2 in Childhood Wilms Tumor: Mechanism to Medicines	\$1,200,000	IIRACC A	2.1

Rank	App ID	Organization/Company	Application Title	Award Amount	Mech.	Overall Score
			Carbamoyl Phosphate Synthase-1:			
17	RP160089	The University of Texas Southwestern Medical Center	A new metabolic liability in non-	000 000	IIRA	2.1
1 /	KP100089		small cell lung cancers De-Orphanizing TLX: Implications	\$900,000	IIKA	2.1
18	RP160501	The Methodist Hospital Research Institute	for Glioblastomas	\$878,969	IIRA	2.1
10	100001	The University of Texas	Ter Gricolastorias	\$070,505	mui	2.1
19	RP160622	Southwestern Medical Center	Computational live cell histology	\$392,779	IIRACB	2.1
20	RP160097	Baylor College of Medicine	Cancer Prevention Post- Graduate Training Program in Integrative Epidemiology	\$2,986,890	RTA	2.1
21	RP160015	The University of Texas Health Science Center at Houston	Collaborative Training of a New Cadre of Innovative Cancer Prevention Researchers	\$4,000,000	RTA- Renewal	2.1
22	RP160340	The University of Texas Southwestern Medical Center	The role of the Lats kinases in sarcomatoid renal cell	\$899,598	IIRA	2.2
23	RP160183	The University of Texas M. D. Anderson Cancer Center	Exploiting molecular and metabolic dependencies to optimize personalized therapeutic approaches	\$900,000	IIRA	2.2
24	RP160232	The University of Texas M. D. Anderson Cancer Center	Understanding Biological and Physical Factors Affecting Response to Proton Therapy to Improve its Clinical Effectiveness	\$879,362	IIRA	2.2
25	RP160022	Baylor College of Medicine	Role of Cohesin in Hematopoiesis and Myeloid Leukemia in Children with Down Syndrome	\$1,905,638	IIRACC A	2.2
26	RP160242	The University of Texas M. D. Anderson Cancer Center	Mechanisms and targeting strategies for SWI/SNF mutations in cancer	\$900,000	IIRA	2.3
27	RP160440	The University of Texas Southwestern Medical Center	Targeting the undruggable: a first- in- class inhibitor of the HIF-2 transcription factor	\$899,412	IIRA	2.3
28	RP160145	The University of Texas M. D. Anderson Cancer Center	Early Detection of Ovarian Cancer with Tumor Associated Proteins and Autoantibodies	\$1,497,595	IIRAP	2.3
29	RP160013	The University of Texas M. D. Anderson Cancer Center	Visualizing T-cell trafficking	\$900,000	IIRA	2.3
30	RP160019	The University of Texas M. D. Anderson Cancer Center	An Adaptive Personalized Clinical Trial using a Patient-Derived Xenograft Strategy to Overcome Ibrutinib Resistance in Mantle Cell	\$841,606	IIRA	2.3
31	RP160051	Texas A&M University System Health Science Center	Improving contrast for antibody- based tumor detection using PET	\$887,134	IIRA	2.3
32	RP160023	The University of Texas M. D. Anderson Cancer Center	Investigating the genetic and molecular mechanisms underlying RAS/ERK substrate network	\$900,000	IIRA	2.4
33	RP160211	The University of Texas Southwestern Medical Center	Novel tumorigenic mechanisms of the LKB1 tumor suppressor in endometrial and cervical cancer	\$896,653	IIRA	2.4

Rank	App ID	Organization/Company	Application Title	Award Amount	Mech.	Overall Score
		The University of Texas	Role of PARP-1 in Estrogen Receptor Enhancer Function and			
34	RP160319	Southwestern Medical Center	Gene Regulation Outcomes in Breast	\$884,315	IIRA	2.4
35	RP160124	The University of Texas Health Science Center at San Antonio	Chemoprevention of Colon Cancer by Anti-inflammatory Blockade Using Neem	\$899,617	IIRAP	2.4
36	RP160188	The University of Texas M. D. Anderson Cancer Center	Regulation of infiltration and function of tumor-resident CD8 T	\$828,060	IIRA	2.4
37	RP160255	The University of Texas Southwestern Medical Center	Structural and Functional Analyses of the Spindle Checkpoint	\$900,000	IIRA	2.5
38	RP160307	The University of Texas Southwestern Medical Center	Targeting Metastatic Pathways	\$900,000	IIRA	2.5
39	RP160517	The University of Texas M. D. Anderson Cancer Center	Exosomal DNA as a surrogate biomarker for early diagnosis and therapeutic stratification in pancreatic cancer	\$891,938	IIRA	2.5
40	RP160345	Baylor College of Medicine	Engineering T cells to ensure specificity for tumor cells and their environment	\$900,000	IIRA	2.5
41	RP160482	The University of Texas M. D. Anderson Cancer Center	Nanoparticle Targeted STAT3 Immune Expression	\$888,429	IIRA	2.6
42	RP160121	The University of Texas M. D. Anderson Cancer Center	Clinical Safety and Efficacy of Third party, fucosylated, cord blood derived regulatory T cells to prevent graft versus host disease	\$900,000	IIRA	2.6
43	RP160520	The University of Texas Southwestern Medical Center	Effect of Chest Radiation Therapy on Cardiomyocyte Turnover	\$897,570	IIRAP	2.6
44	RP160268	The University of Texas Southwestern Medical Center	DNA damage-induced small non- coding RNAs: mechanism and their role in cancer development	\$900,000	IIRA	2.7
45	RP160512	The University of Texas Health Science Center at San Antonio	Integrin-mediated IL-18 signaling in the prevention and treatment of inflammation-associated colorectal cancer	\$859,620	IIRA	2.7
46	RP160577	Baylor Research Institute	A novel function of Itch in controlling IL-17-induced inflammation in colon cancer	\$900,000	IIRA	2.7
47	RP160617	The University of Texas at Dallas	Optimizing therapeutic strategies against lung cancer using Multi- Modality Characterization and	\$899,999	IIRA	2.7
48	RP160493	The University of Texas Southwestern Medical Center	pharmacological targeting of the oncogenic activity of Jumonji	\$899,997	IIRA	2.8
49	RP160054	Baylor College of Medicine	The CTC Circulator Phenotype: Insights into Mechanisms of Breast Cancer Dormancy	\$884,332	IIRA	2.9
50	RP160235	The University of Texas Health Science Center at Houston	Regulation of tumor aggressiveness and immune suppression in lung adenocarcinoma	\$900,000	IIRA	2.9

Rank	App ID	Organization/Company	Application Title	Award Amount	Mech.	Overall Score
			Radiogenomic Screen to Identify			
			Novel Proliferation-associated			
			Glioblastoma Genomic Therapeutic			
		The University of Texas M. D.	Targets: Discovery and Mechanistic			
51	RP160150	Anderson Cancer Center	Validation Study	\$897,627	IIRA	3.0
			High resolution imaging for early			
52	RP160460	Rice University	and better detection of bladder	\$873,765	IIRAP	3.0
		The University of Texas M. D.	Identifying new epigenetic			
53	RP160471	Anderson Cancer Center	vulnerabilities in pancreatic	\$900,000	IIRA	3.1
			Systematic identification of small			
			molecule inhibitors that			
54	RP160462	Baylor College of Medicine	manipulate telomerase activities	\$898,288	IIRA	3.2
			The role of Prdm16 and histone H3			
			lysine 9 methyltransferase complex			
55	RP160035	Baylor College of Medicine	in MDS	\$872,157	IIRA	3.2

^{*}RP160237 - The peer review panel recommended reducing the budget to \$300,000 per year for 3 years for a total of \$900,000 based on the scope and depth of the work proposed.

Academic Research Recruitment Grant Award Recommendations

Rank	App ID	Candidate	Organization/Company	Mech.	Budget Requested	Overall Score
			The University of Texas Health			
1	RR160019	Dung-fang Lee	Science Center at Houston	RFT	\$2,000,000	1.0
2	RR160020	Wei Yang	The University of Texas at Austin	REI	\$6,000,000	1.0
		<u>y</u>			, , , , , , , , , , , , , , , , , , , ,	
	DD160022	4 1 D DI:	The University of Texas M. D.	DDC	Φ4.000.000	1.0
3	RR160022	Andrew D. Rhim	Anderson Cancer Center	RRS	\$4,000,000	1.8
4	RR160017	Zhijie Liu	The University of Texas Health Science Center at San Antonio	RFT	\$2,000,000	2.5
			The University of Texas M. D.			
5	RR160021	Nidhi Sahni	Anderson Cancer Center	RFT	\$2,000,000	2.5

RFT = Recruitment of First-Time, Tenure-Track Faculty Members

REI = Recruitment of Established Investigators

RRS = Recruitment of Rising Stars

^{**}RP160190 - The peer review panel recommended not funding Aim 4 (Pilot prospective clinical trial) and reducing the budget to \$300,000 per year for 3 years for a total of \$900,000. The final score was based on revised scope with full deletion of Aim 4.

^{***}RP160249 - The peer review panel recommended that given the absence of a clinical trial, the budget should be reduced to \$300,000 per year for 4 years for a total of \$1,200,000.

Product Development Research Award Recommendation -

The PIC unanimously recommends approval of one product development grant proposal totaling \$20,000,000. The recommended grant proposal was submitted in response to the New Company Product Development Award Request for Applications. The Product Development Council (PDRC) recommended one application to the PIC. The PDRC provided its recommendation to the presiding officers on October 26, 2015.

The PIC is required to give funding priority, to the extent possible, to applications that meet one or more criteria set forth in V.T.C.A., TEX. HEALTH & SAFETY CODE § 102.251(a)(2)(C). The PIC determined that these product development proposals met the following CPRIT funding priorities:

- could lead to immediate or long-term medical and scientific breakthroughs in the area of cancer prevention or cures for cancer;
- strengthen and enhance fundamental science in cancer research;
- Ensure a comprehensive coordinated approach to cancer research and cancer prevention;
- are interdisciplinary or interinstitutional (the PIC chose this factor for Established Company Awards);
- address federal or other major research sponsors' priorities in emerging scientific or technology fields in the area of cancer prevention, or cures for cancer;
- are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;
- are collaborative between any combination of private and nonprofit entities, public or private agencies or institutions in this state, and public or private institutions outside this state;
- have a demonstrable economic development benefit to this state;
- expedite innovation and product development, attract, create, or expand private sector entities that will
 drive a substantial increase in high-quality jobs, and increase higher education applied science or
 technology research capabilities; and
- address the goals of the Texas Cancer Plan.

Product Development Research Grant Award Recommendation

Rank	Application ID	Company Name	Project	Requested Budget	Overall Score
1	DP150127	Ruga Corporation	Engineered AXL Decoy Receptor for Treatment of AML & Solid Tumors	\$20,000,000	2.2

Prevention Award Recommendations -

The PIC unanimously recommends approval of 12 prevention grant proposals totaling \$13,247,742. The recommended grant proposals were submitted in response to Evidence-Based Cancer Prevention Services-Colorectal Cancer Prevention Coalition, Competitive Continuation/Expansion-Evidence-Based Cancer prevention Services, Cancer Prevention Promotion and Navigation to Clinical Services, Dissemination of CPRIT-Funded Cancer Prevention and Control Interventions; and Evidence-Based Cancer Prevention Services Request for Applications. The PIC followed the recommendations made by the Prevention Review Council (PRC), including deferring two applications to a future PIC meeting. The PRC provided the prioritized list of recommendations for the prevention awards to the presiding officers on October 27, 2015.

The PIC is required to give funding priority, to the extent possible, to applications that meet one or more criteria set forth in V.T.C.A., TEX. HEALTH & SAFETY CODE § 102.251(a)(2)(C). The PIC determined that these prevention proposals met the following CPRIT funding priorities:

- ensure a comprehensive coordinated approach to cancer research and cancer prevention;
- are interdisciplinary or interinstitutional;
- address federal or other major research sponsors' priorities in emerging scientific or technology fields in the area of cancer prevention or cures for cancer;
- are collaborative between any combination of private and nonprofit entities, public or private agencies or institutions in this state, and public or private institutions outside this state;
- have a demonstrable economic development benefit to this state; and
- address the goals of the Texas Cancer Plan.

Prevention Grant Award Recommendations

See pages 9-18 for the prevention grant award recommendations.

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP160049	CCE- EBP	Expansion of a comprehensive cervical cancer screening program for medically underserved women in Harris County	Anderson, Matthew L	Baylor College of Medicine	\$1,500,000	1.9			1	
PP160047	CCE- EBP	A community based program to increase breast and cervical cancer screening and HPV vaccination to reduce the impact of breast and certical cancer among Latinas	Savas, Lara S	The University of Texas Health Science Center at Houston	\$1,387,005	2.7	Steps that will be taken to assess actual # of screenings and vaccinations for participants in educational sessions are not explained. It appears that only women completing the surveys will be followed. Evaluation of outcomes for all	Changes not recommended-PRC reviewed peer review comments and determined those comments did NOT impact decision to recommend or impact rank order	2	

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							participants is not provided, only provided for women completing surveys. Budget is unclear about number of screenings that will be paid for; number of financially supported screening isn't clearly stated.			
PP160042	ЕВР	Using Best Practices to Promote HPV vaccination in Rural Primary Care Settings	Parra- Medina, Deborah	The University of Texas Health Science Center at San Antonio	\$1,295,493	2.8	Outcomes evaluation doesn't have baseline and % increase noted. A highly intensive program is being implemented and the high cost is a barrier. If the cost is reduced, the	changes not recommended- PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	3	

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							applicability of the proposed approach may be enhanced. Reviewers would like the applicants to clarify why the increase in the budget from the previous grant to this grant. Why has the per person cost increased so much?			
PP160032	PN	Family Health History-based Colorectal Cancer Prevention and Navigation to Clinical Services among Uninsured Chinese	Chen, Lei- Shih	Texas A&M University	\$399,993	3.0	Findings from this study should be applied to follow-up treatment for the participants. Plans for this are lacking and should be provided.	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	4	

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
		Americans in Texas								
PP160056	PN	REACH Rural Education and Awareness for Community Health	Hoelscher, Bill	Coastal Bend Wellness Foundation	\$379,698	3.0	Should be clarified that \$25 gift card is not being offered to change the behavior of the participants.	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	5	
PP160010	EBP	Maximizing opportunities for HPV vaccination in the Golden Triangle	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	\$1,409,909	3.1	Ask applicants why they do not plan to vaccinate young adults on college campuses. In addition, students	changes not recommended-PRC reviewed peer review comments and determined they did not impact	6	

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							could be used to help with recruitment	decision to recommend or impact rank order		
PP160048	DI	Training CHWs for More Effective Cancer Education and Navigation	Bolin, Jane N	Texas A&M University System Health Science Center	\$300,000	3.1			7	
PP160023	EBP- CRC	Optimizing Colorectal Cancer Screening in East Texas	Sauter, Edward	The University of Texas Health Center at Tyler	\$2,299,753	3.3	Recommendation was made in previous application that providing FIT isn't evidence-based for people who are at significant risk for CRC; this isn't consistent with ACS guidelines. Ask how they came	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	8	

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							up with \$275/colonoscopy			
PP160036	CCE- EBP	Establishing a Comprehensive Cancer Prevention and Support Program within Asian American Communities in Houston and Austin Areas of Texas	Sun, Helen	Light and Salt Association	\$1,101,986	3.3	Request that the applicant provides a leadership plan that includes input from the three communities being targeted: Vietnames, Korean, and Filipino	changes not recommended-PRC reveiwed peer review comments and determined they did not impact decision to recommend or impact rank order	9	
PP160027	EBP	Improving Service Delivery to Cancer Survivors in	Foxhall, Lewis E	The University of Texas M. D. Anderson	\$1,374,127	3.5	Not clear how project will add to what is already happening in clinic. This is a large, complex project and not clear how	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to	10	Recommended out of score order above one with higher score due to

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
		Primary Care Settings		Cancer Center			it will be managed on a daily basis. Budget is weak and justification for some of the positions is lacking	recommend or impact rank order		ROI and cancer type
PP160051	DI	Dissemination of an Evidence- Based HPV Vaccination Intervention in Community and Clinical Settings	Fernandez, Maria E	The University of Texas Health Science Center at Houston	\$299,778	3.6	List of current awards doesn't specify PD participation; it should be verified that PD isn't overcommitted. Budget seems somewhat personnel heavy and accounts for a large majority of voerall costs; careful review of personnel and their exact roles and responsibilities and whether or not	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	11	Recommended out of score order above one with higher score due to type of program

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							any of the services are duplicative may be warranted.			
PP160011	CCE- EBP	GRACIAS Texas: Genetic Risk Assessment for Cancer in All South Texas	Tomlinson, Gail E	The University of Texas Health Science Center at San Antonio	\$1,500,000	2.7			12	Recommended but ranked out of score order due to 1) ROI may be limited; large numbers need to be screened to identify at risk pop.

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP160046	EBP	Using social marketing and mobile school-based vaccination clinics to increase HPV vaccination uptake in highrisk geographic areas	Cuccaro, Paula	The University of Texas Health Science Center at Houston	\$1,499,668	2.2			13	Recommended but out of score order due to 1) geography- several HPV grants in Harris county, 2) ROI- costs for education vs services
PP160033	CCE- EBP	Increasing cancer control behaviors among the underserved: A collaboration with Texas 2-1-1 programs	Fernandez, Maria E	The University of Texas Health Science Center at Houston	\$1,499,989	2.4			14	Recommended but out of score order due to 1) geographyseveral HPV grants in Harris county, 2) cancer typeavailabilty of breast and cervical services 3) ROI-costs for

App ID	Mech.	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
										education vs services
				Initial funding (Rank #1- 12)	\$13,247,742					
				(Rank #13+14) 2nd funding	\$2,999,657 \$16,247,399					



MEMORANDUM

To: OVERSIGHT COMMITTEE MEMBERS

From: VINCE BURGESS, CHIEF COMPLIANCE OFFICER

Subject: COMPLIANCE CERTIFICATION – NOVEMBER 2015 AWARDS

Date: NOVEMBER 04, 2015

Summary and Recommendation:

As CPRIT's Chief Compliance Officer, I am responsible for reporting to the Oversight Committee regarding the agency's compliance with applicable statutory and administrative rule requirements during the grant review process. I have reviewed the compliance pedigrees for the grant applications submitted to CPRIT for the:

- Recruitment of First-Time, Tenure-Track Faculty Members
- Recruitment of Established Investigators
- Recruitment of Rising Stars
- Individual Investigator Research Awards
- Individual Investigator Research Awards for Computational Biology
- Individual Investigator Research Awards for Cancer in Children and Adolescents
- Individual Investigator Research Awards for Prevention and Early Detection
- Research Training Awards
- New Company Product Development Awards
- Evidence-Based Prevention Services
- Competitive Continuation/Expansion-Evidence-Based Prevention Services
- Evidence-Based Cancer Prevention Services-Colorectal Cancer Prevention Coalition
- Cancer Prevention Promotion and Navigation to Clinical Services
- Dissemination of CPRIT-funded Cancer Prevention and Control Interventions

I have conferred with staff at CPRIT and SRA International (SRA), CPRIT's contracted third-party grants administrator, regarding academic research, product development research, and prevention awards and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings. I am satisfied that the application review process that resulted the above mechanisms recommended by the Program Integration Committee (PIC), followed applicable laws and agency administrative rules. I note that the following mechanisms received applications; however, none were recommended by the review councils or considered by the PIC: Established Company Product Development Awards and Company Relocation Product Development Awards. I

certify the academic research, prevention, and product development award recommendations for the Oversight Committee's consideration.

Background:

CPRIT's Chief Compliance Officer must report to the Oversight Committee regarding compliance with the statute and the agency's administrative rules. Among the Chief Compliance Officer's responsibilities is the obligation "to ensure that all grant proposals comply with this chapter and rules adopted under this chapter before the proposals are submitted to the oversight committee for approval." Texas Health & Safety Code § 102.051(c) and (d).

CPRIT uses a compliance pedigree process to formally document compliance for the grant award process. The compliance pedigree tracks the grant application as it moves through the review process and documents compliance with applicable laws and administrative rules. A compliance pedigree is created for each application; the information related to the procedural steps listed on the pedigree is entered and attested to by SRA employees and CPRIT employees. To the greatest extent possible, information reported in the compliance pedigree is imported directly from data contained in CPRIT's Application Receipt System (CARS), the grant application database managed by SRA. This is done to minimize the opportunity for error caused by manual data entry.

No Prohibited Donations:

Although CPRIT is statutorily authorized to accept gifts and grants pursuant to Texas Health & Safety Code § 102.054, the statute prohibits CPRIT from awarding a grant to an applicant who has made a gift or grant to CPRIT or a nonprofit organization established to provide support to CPRIT. I note that Texas Health & Safety Code § 102.251(a)(3) specifically addresses "donors from any nonprofit organization established to provide support to the institute compiled from information made available under § 102.262(c)." To the best of my knowledge, there are no nonprofit organizations that have been established to provide support to CPRIT on or after June 14, 2013, the effective date of this statutory change. The only nonprofit organization established to provide support to the Institute was the CPRIT Foundation; however, the CPRIT Foundation ceased operations and changed its name and its purpose prior to June 14, 2013. The institute has received no donations from the CPRIT Foundation made on or after June 14, 2013.

I have reviewed the list of donors to CPRIT maintained by CPRIT's accountant and compared the donors to the list of applicants. No donors to CPRIT have submitted applications for grant awards during the award cycles that are the subject of this report.

Pre-Receipt Compliance:

The activities listed in pre-receipt stage cover the period beginning with CPRIT's issuance of the Request for Application (RFA) through the submission of grant applications. CPRIT's administrative rules require that RFAs be publicly posted in the *Texas Register*. The RFA

specifies a deadline and mandates that only those applications submitted electronically through CARS are eligible for consideration. CARS blocks an application from being submitted once the deadline passes. Occasionally, an applicant may have technical difficulties that prevent the applicant from completing the application submission. When this occurs, the applicant may request that the deadline be extended to allow for a late submission. The applicant's request is submitted to the CPRIT Helpdesk that is managed by SRA; the program officer considers any requests for extension and may approve an extension for good cause. When an extension request is approved, the applicant is notified and CARS is reopened for a brief period – usually two to three hours – the next business day.

<u>Academic Research:</u>

I note that four applications were received in response to the Recruitment of First-Time, Tenure Track Faculty members RFA, one application was received for the Recruitment of Established Investigators RFA, and one application was received for the Recruitment of Rising Starts RFA. In response to the academic, non-recruitment RFAs, CPRIT received 504 applications. Six applications were administratively withdrawn prior to Peer Review. In addition, based on the scores of a preliminary evaluation, 211 academic, non-recruitment applications did not move forward for discussion at the in-person peer review phase. I reviewed the application pedigrees for the six recruitment applicants and 287 academic research, non-recruitment applications that underwent peer review. It should be noted that one academic research, non-recruitment application was voluntarily withdrawn by the applicant during the Peer Review process.

All academic research RFAs were posted in the Texas Register and all applications were submitted through CARS. Three applicants requested an extension to submit applications past the deadline. The program officer determined that good cause supported two requests and the deadline was extended. One application was denied an extension. None of the applications that requested an extension were recommended for a grant award.

Product Development Research:

Ten applications were received in response to the New Company RFA, five applications were received for the Company Relocation RFA, and one application was received in response to the Established Company RFA. Of the applications submitted for New Company awards, one application was administratively withdrawn prior to primary reviewer assignment. All applicants recommended for awards paid the application fee. The product development research RFAs were published in the Texas Register and applications submitted through CARS. One applicant requested an extension to submit the application after the deadline. The program officer determined that good cause supported the request and the deadline was extended. The application that received the extension was not recommended for a grant award.

Prevention:

Six applications were received in response the Evidence-Based Prevention Services RFA, six applications were received in response to the Competitive Continuation/Expansion-Evidence Based Cancer Prevention Services, one application was received for the Evidence-Based Prevention Services-Colorectal Cancer Prevention Coalition RFA, five applications were received for the Cancer Prevention Promotion and Navigation to Clinical Services RFA, and two were received for the Dissemination of CPRIT-funded Cancer Prevention and Control Interventions RFA. A total of two applications withdrew before review — one was withdrawn administratively and one was withdrawn by the applicant. The RFAs were published in the Texas Register and all applications were submitted through CARS. One applicant requested an extension to submit the application after the deadline. The program officer determined that good cause supported the request and the deadline was extended. The application that received the extension was not recommended for a grant award.

Receipt, Referral, and Assignment Compliance:

Once applications have been submitted through CARS, SRA staff reviews the applications for compliance with RFA directions. If an applicant does not comply with the directions, SRA notifies the program officer and the program officer makes the final decision whether to administratively withdraw the application. Recruitment grant applications are assigned to the Scientific Review Council members for peer review. All other academic research, product development research, and prevention applications are assigned to their respective peer review panels. Prior to distribution of the applications, reviewers are given summary information about the applicant, including the Project Director and collaborators. Reviewers must sign a conflict of interest agreement and confirm that they do not have a conflict of interest with the application before they are provided with the full application.

The pedigrees attest that a conflict of interest statement was signed by each primary reviewer for each Grant Application.

As previously mentioned, six applications were administratively withdrawn and one was withdrawn by the applicant during the 16.1 academic research cycle. Of the applications received in response to 16.1 prevention RFAs, one was administratively withdrawn and one was withdrawn by the applicant. One application was administratively withdrawn during the 15.4 product development cycle.

Peer Review:

Primary reviewers (typically three) must submit written critiques for each of their assigned applications prior to the peer review meeting. After the peer review meetings, a final score report from the review committee is delivered to the Review Council for additional review. Following the peer review meeting, each participating peer reviewer must sign a post-review peer review statement

certifying that the reviewer knew of and understood CPRIT's conflict of interest policy and followed the policy for this review process.

Academic Research:

For the Recruitment Awards, the applications are reviewed by the Scientific Review Council (SRC), which assigns two members of the SRC to be primary reviewers. I reviewed the peer reviewer critiques and supporting documentation, such as the sign-out sheets, third-party observer reports, and post-review peer reviewer statements. Sign out sheets are used to document when a reviewer with a conflict of interest associated with a particular application leaves the room (or disengages from the conference call) during the discussion and scoring of the application. A conflict of interest was declared for one recruitment application reviewed by the SRC. The reviewer disengaged from the conference call and did not participate in the discussion of the application.

Academic Research applications (non-recruitment) are reviewed by peer review panels and recommended to the Scientific Review Council. As documented by SRA, reviewers with conflicts of interest did not participate in review of those applications. I reviewed supporting documentation, such as conflict of interest statements (COIs), third-party observer reports, and sign out sheets. All declared COIs left the room or disengaged from the conference call and did not participate in the discussion of relevant application(s).

I also reviewed and confirmed that the post review conflict of interest statements were signed by peer review members as well as the six SRC members that attended the Review Council meeting on October 23, 2015.

Product Development Research:

Product Development Research awards go through a peer review teleconference screening call to determine which applications will be invited to in-person review. Those applicants that attend in-person review are once again evaluated by peer reviewers. Applicants recommended after in-person review must then go through due diligence, which is conducted by outside contractors and outside intellectual property counsel. The Product Development Review Council (PDRC) recommends awards after due diligence to the PIC. I have verified from SRA documentation that those reviewers with conflicts did not participate in review of applications for which they indicated a conflict of interest.

I also reviewed and confirmed that the post review conflict of interest statements were signed by peer review members as well as the seven PDRC members that attended the Review Council meeting on October 12, 2015.

Prevention:

Prevention applications are reviewed by peer review panels and then sent to the Prevention Review Council. Reviewers with a conflict of interest with an application did not participate in review of that application, which is documented by SRA.

I also reviewed and confirmed that the post review conflict of interest statements were signed by peer review members as well as the three PRC members that attended the Review Council meeting on October 23, 2015.

Programmatic Review:

Programmatic review is conducted by the Scientific Review Council, Prevention Review Council, and Product Development Review Council for their respective awards. Each review council creates a final list of grant applications it will recommend to the PIC for grant award slates.

For each program, I reviewed that the recommendations correspond to RFAs that have been released and that the pedigrees reflect the date of the review council meeting and that the applications were recommended by the corresponding review council.

To the extent that any Review Council member identified a conflict of interest, I reviewed documentation confirming that the review council member did not participate in the discussion or vote on the application(s).

I also reviewed the third-party observer reports for each review panel and review council meeting. The third-party observer reports document that the panel and review council discussions were limited to the merits of the applications and established evaluation criteria and that conflicted reviewers exited the room or the conference call when the application was discussed.

Academic Research:

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. Each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. No individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1 for example, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not be recommended. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

The SRC met on October 23, 2015 to consider the applications recommended by the peer review panels following their meetings that were held on September 29 – October 7, 2015. After considering success rates across panels, the SRC decided to reduce success rates in four of the panels to fall in line with the other three panels. This resulted in some applications not being recommended for grant awards that received scores equal to or more favorable than some applications that were recommended for grant awards. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding.

Product Development Research:

For this cycle, three applications went through due diligence. The Product Development Review Council recommended one of those three applications to the PIC.

Prevention:

Some applications with more favorable or equivalent scores to applications that were recommended for awards did not move forward to the PIC. As allowed in 25 T.A.C § 703.6(d)(1), the Prevention Review Council's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio. The Prevention Review Council's recommendations considered geographical impact, cancer site of the applications as compared to the overall Prevention portfolio, and cost. The letter and rank order list from the Prevention Review Council's Chair explains why some recommended grant applications were ranked ahead of an application with a more favorable score as required by 25 T.A.C. § 703.6(d)(2)(B).

Program Integration Committee (PIC) Review:

Texas Health & Safety Code § 102.051(d) requires the Chief Compliance Officer to attend and observe the PIC meetings to ensure compliance with CPRIT's statute and administrative rules. CPRIT's statute requires that, at the time the PIC's final Grant Award recommendations are formally submitted to the Oversight Committee, the Chief Executive Officer shall prepare a written affidavit for each Grant Application recommended by the PIC containing relevant information related to the Grant Application recommendations.

I attended the November 3, 2015, PIC meeting as an observer and confirm that the PIC review process complied with CPRIT's statute and administrative rules. The PIC considered 75 applications; 73 were recommended to move forward to the Oversight Committee. Two applications were recommended to be deferred until a subsequent PIC meeting. A review of the CEO affidavits confirms that such affidavits were executed and provided for each Grant Application recommendation.

Academic Research

Recommendation

Items

Academic Research Awards Summary

Review Council Chairman Letter – Individual Investigators & Training Awards

Review Council Chairman Letter – Recruitment Awards





CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: MARGARET KRIPKE, PH.D.

SUBJECT: FY16, CYCLE 1 RESEARCH AWARDS

DATE: NOVEMBER 3, 2015

The applications recommended for funding have been reviewed and approved by the CPRIT Scientific Review Council (SRC), as well as the Program Integration Committee (PIC). Applications were submitted in response to five scientific research award mechanism Request for Applications (RFAs): Individual Investigator Research Award (RFA R-16-IIRA-1), Individual Investigator Research Award for Computational Biology (RFA R-16-IIRACB-1), Individual Investigator Research Award for Cancer in Children and Adolescents (RFA R-16-IIRACCA-1), Individual Investigator Research Award for Prevention and Early Detection (RFA R-16-IIRAP-1), and Research Training Awards (RFA R-16-RTA-1). Five hundred and four applications were received in total for all mechanisms. Six applications were administratively withdrawn, and 498 were reviewed (IIRA – 347, IIRACB – 50, IIRACCA – 44, IIRAP – 44, and RTA – 13 [7 new and 6 renewal]). Fifty-five applications are being recommended for funding, for a combined amount of \$62,761,270.

Individual Investigator Research Award (RFA R-16-IIRA-1)

Applications Receiving Preliminary Evaluation: 347 Applications Receiving Full Review: 135 Applications Recommended: 39

Total Funding Request: \$34,744,442

The aim of this RFA is to support innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. The goal of awards made in response to this RFA is to fund exceptionally innovative research projects with great potential impact that are directed by a single investigator. Areas of interest include laboratory research, translational studies, and/or clinical investigations. The degree of relevance to cancer research is an important criterion for evaluation of projects for funding. Awards are made in the amount of up to \$300,000 per year for three years for a maximum of \$900,000.

The applications were evaluated and scored by members of the seven Research Peer Review Panels. Due to the large number of applications submitted for consideration, CPRIT elected to use a preliminary evaluation process to conduct an initial screening of the proposals. In the preliminary evaluation stage, the assigned reviewers focus on a subset of material presented in the application—the Abstract and

Significance, Layperson Summary, Budget and Justification, and Biographical Sketches. Applications that do not sufficiently capture the reviewers' interest or have been judged to offer only modest contributions to the field of cancer research at the preliminary evaluation stage are not considered for further review.

After preliminary review, 211 (61%) of the applications were eliminated from further consideration. The remaining 136 applications were subjected to full review (one application was withdrawn after preliminary evaluation and only received a partial full review leaving a total of 135 receiving a full review), and 42 were recommended to the Scientific Review Council for their consideration. The Scientific Review Council voted to recommend 39 of the 42 to be considered for approval by the Oversight Committee.

Questions considered by reviewers included the following: Will the results of this research significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for cancer patients? Is the application innovative? Does the project develop new technologies, methods, tools, or resources for cancer research or address important under-explored areas? Will the project lead to truly substantial advances in the field? Is the research plan supported by sufficient preliminary data or scientific rationale? Are the methods appropriate? Does the Principal Investigator demonstrate creativity and sufficient expertise? Does the proposed research have a high degree of relevance to cancer research?

Individual Investigator Research Award for Computational Biology (RFA R-16-IIRACB-1)

Applications Receiving Preliminary Evaluation: N/A
Applications Receiving Full Review: 50
Applications Recommended: 1

Total Funding Request: \$392,779

The aim of this RFA is to support innovative mathematical or computational research projects addressing questions that will advance our knowledge in any aspect of cancer. Areas of interest include data analysis of cellular pathways, microarrays, cellular imaging, cancer imaging, or genomic, proteomic, and metabolomic databases; descriptive mathematical models of cancer, as well as mechanistic models of cellular processes and interactions and use of artificial intelligence approaches to build new tools for mining cancer research and treatment databases. Awards are made in the amount of up to \$150,000 per year for three years for a maximum of \$450,000.

The applications were evaluated and scored by members of the seven Research Peer Review Panels. IIRACB applications did not go through the preliminary review process. Three applications were recommended to the Scientific Review Council for their consideration. The Scientific Review Council voted to recommend 1 of the 3 to be considered for approval by the Oversight Committee.

Questions considered by reviewers included the following: Will the results of this research, if successful, significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for patients? Is the project innovative? Does the project propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important underexplored or unexplored areas? If the research project is

successful, will it lead to truly substantial advances in the field rather than add modest increments of insight?

<u>Individual Investigator Research Award for Cancer in Children and Adolescents (RFA R-16-IIRACCA-1)</u>

Applications Receiving Preliminary Evaluation: N/A
Applications Receiving Full Review: 44
Applications Recommended: 5

Total Funding Request: \$6,105,638

The aim of this RFA is to support innovative research projects addressing questions that will advance our knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. The goal of these awards is to produce outcomes that will reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near or long term. The subject of applications addressed: the causes of cancer in children and adolescents, including genetic factors or prenatal exposure to environmental agents; identification of risk factors for cancer development; new methods for diagnosing cancers in children and/or adolescents; development of new therapies, including targeted therapies, immunotherapies, and new drugs; identification of patients at risk of developing late effects of cancer treatment; and improvements in quality of life for survivors of childhood and adolescent cancers. Awards are made in the amount of up to \$500,000 per year for four years for a maximum of \$2,000,000.

The applications were evaluated and scored by members of the seven Research Peer Review Panels. IIRACCA applications did not go through the preliminary review process. Six applications were recommended to the Scientific Review Council for their consideration. The Scientific Review Council voted to recommend 5 of the 6 to be considered for approval by the Oversight Committee.

Questions considered by reviewers included the following: Will the results of this research significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for cancer patients? Is the application innovative? Does the project develop new technologies, methods, tools, or resources for cancer research or address important under-explored areas? Will the project lead to truly substantial advances in the field? Is the research plan supported by sufficient preliminary data or scientific rationale? Are the methods appropriate? Does the Principal Investigator demonstrate creativity and sufficient expertise? Does the proposed research have a high degree of relevance to cancer research? Does the proposed research address cancer in children or adolescents? Is it likely to make an impact on these diseases?

Individual Investigator Research Award for Prevention and Early Detection (RFA R-16-IIRAP-1)

Applications Receiving Preliminary Evaluation: N/A
Applications Receiving Full Review: 44
Applications Recommended: 6

Total Funding Request: \$6,552,003

The aim of this RFA is to support innovative research projects addressing questions that will advance our knowledge of the causes, prevention, early-stage progression, and/or early detection of cancer. The goal of these awards is to support activities that will reduce the burden of cancer in the near or long

term. The subject of applications addressed: environmental carcinogenesis, including high-throughput methods for carcinogen detection and identification of carcinogens and their mechanisms of action; the role of microbial agents in cancer causation; cancer epidemiology; identification of populations at high risk of developing cancer; cellular and molecular alterations leading to development of precancerous lesions; approaches to prevent progression of early lesions; methods for early detection of cancer; development and testing of intervention strategies to increase access to and improve recently endorsed screening technologies for cancer; cancer-focused health services/outcomes or patient-centered outcomes research; and development and adaptation of novel interventions for effective and efficient delivery of cancer prevention and screening services. Awards are made in the amount of up to \$300,000 in total costs per year for up to 3 years for laboratory and clinical research for a maximum of \$900,000, and up to \$500,000 in total costs per year for up to 3 years for population-based research for a maximum of \$1,500,000.

The applications were evaluated and scored by members of the seven Research Peer Review Panels. IIRAP applications did not go through the preliminary review process. Nine applications were recommended to the Scientific Review Council for their consideration. The Scientific Review Council voted to recommend 6 of the 9 to be considered for approval by the Oversight Committee.

Questions considered by reviewers included the following: Will the results of this research significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for cancer patients? Is the application innovative? Does the project develop new technologies, methods, tools, or resources for cancer research or address important under-explored areas? Will the project lead to truly substantial advances in the field? Is the research plan supported by sufficient preliminary data or scientific rationale? Are the methods appropriate? Does the Principal Investigator demonstrate creativity and sufficient expertise? Does the proposed research have a high degree of relevance to cancer research? Does the proposed research have a high degree of relevance to cancer prevention research or early detection?

Research Training Awards (RFA R-16-RTA-1)

Applications Receiving Preliminary Evaluation: N/A

Applications Receiving Full Review: 13 (6 renewal and 7 new)
Applications Recommended: 4 (3 renewal and 1 new)

Total Funding Request: \$14,966,408

The aim of this RFA is to support integrated institutional research training programs to support promising individuals who seek specialized training in the area of cancer research. CPRIT expects institutions to provide trainees with broad access to research opportunities across disciplinary and departmental lines and to maintain high standards for intellectual rigor and creativity. Applications were accepted for new and renewal projects with applicants being able to submit one application for a basic science training program and one applications for a prevention training program. Awards are made in the amount of up to \$800,000 per year for five years for a maximum of \$4,000,000.

The applications were evaluated and scored by members of the seven Research Peer Review Panels. IIRAP applications did not go through the preliminary review process. Five applications were recommended to the Scientific Review Council for their consideration. The Scientific Review Council voted to recommend 4 of the 5 to be considered for approval by the Oversight Committee.

Questions considered by reviewers for new programs included the following: What is the likelihood that the training program will serve as a sound foundation to enhance a supported trainee's potential for, and commitment to, a productive, independent scientific research career in a cancer-related field? Will the training plan provide trainees with individualized and supervised experiences that will enable them to develop the research skills needed to be independent researchers or physician-scientists? Is the training plan customizable for students from diverse academic backgrounds and differing educational philosophies? Do the PI and mentors have excellent research qualifications and track records of mentoring that are appropriate for the proposed training program? Are high-quality individuals routinely recruited at the applicant institution's existing training programs? Are the qualifications and interests of these potential trainees appropriate for the training program described by the applicant institution? Are there sufficient numbers of highly meritorious potential trainees to fill the slots requested? Is there a plan to enhance the diversity of trainees by recruiting from underrepresented groups? Is there a high-quality institutional environment for the scientific development of trainees? Is there appropriate institutional commitment to fostering training as investigators or physician-scientists?

Questions considered by reviewers for existing programs included the following: Does the proposed continuation of the program demonstrate a high likelihood of success based on the initial program's results and outcomes? Has the applicant sufficiently described results and findings of the previously funded application? What is the likelihood that the training program will continue to serve as a sound foundation to enhance a supported trainee's potential for, and commitment to, a productive, independent scientific research career in a cancer-related field? Has the program recruited underrepresented minority trainees? Has the training plan provided, and will the plan continue to provide, trainees with individualized and supervised experiences that will enable them to develop the research skills needed to be independent researchers or physician-scientists? Is the training plan customizable for students from diverse academic backgrounds and differing educational philosophies? Do the PI and mentors have excellent research qualifications and track records of mentoring that are appropriate for the proposed training program? Have high-quality individuals been recruited into the training programs? Are the qualifications and interests of these potential trainees appropriate for the training program described by the applicant institution? Have there been sufficient numbers of highly meritorious candidates to fill the available slots? Have efforts been made to enhance the diversity of trainees by recruiting from underrepresented groups? Has appropriate progress been demonstrated by trainees? Is there a highquality institutional environment for the scientific development of trainees? Is there appropriate institutional commitment to fostering training as investigators or physician-scientists?

Overall SRC and PIC Research Program Recommendation

During the SRC discussion, it was determined that the success rates (percentage of the number recommended/number reviewed) for four panels were much higher than the rates for the other three panels and higher than the historical approval rates. It was suggested that these four panels reduce their success rates to fall in line with the other panels, and all chairs agreed to the scoring adjustments. This resulted in some applications not being recommended for grant awards that received scores equal to or more favorable than some applications that were recommended for grant awards. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding.

After determining to adjust the success rates, the SRC voted to recommend 55 of the 65 applications that were presented by the Peer Review Panels and to accept any modifications in work scope and budget as recommended. This recommendation was forwarded by the Chair of the SRC to the Program Integration Committee and to the Oversight Committee. The Program Integration Committee met to discuss applications on November 3, 2015 and voted to recommend all applications in the order in which they were presented by the SRC. The PIC accepted all of the modifications in work scope and budget as recommended, and forwarded their recommendation to the Oversight Committee for final approval.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: MARGARET KRIPKE, PH.D.

SUBJECT: FY16 RECRUITMENT AWARDS, CYCLE REC 16.2 AND REC 16.3

DATE: NOVEMBER 3, 2015

The applications recommended for funding by the CPRIT Scientific Review Council (SRC) have been reviewed and approved by the Program Integration Committee (PIC). The applications recommended for funding have been reviewed and approved by the CPRIT Scientific Review Council (SRC). Applications were submitted in response to Recruitment of Established Investigator (REI), Recruitment for First-Time, Tenure Track Faculty Members (RFT), and Recruitment of Rising Stars (RRS) Request for Applications for Recruitment Cycles REC 16.2 and 16.3. Two applications were received for REC 16.2 (RFT - 2). Four applications were received for REC 16.3 (REI-1, RFT-2, and RRS-1). All six applications were reviewed, and no applications were administratively rejected for ineligibility. Five applications in total were recommended for funding by the SRC for both cycles. Three applications for Recruitment of First-Time, Tenure-Track Faculty Members, one for Recruitment of Established Investigators, and one for Recruitment of Rising Stars have been recommended for a combined amount of \$16,000,000.

Recruitment of Established Investigators (RFA R-16-REI)

Applications Reviewed: 1
Applications Recommended: 1

Total Funding Request: \$6,000,000

The aim of this RFA is to recruit outstanding senior research faculty with distinguished professional careers and established cancer research programs to academic institutions in Texas. Award: Up to \$6M over a period of five years.

The applications were evaluated and scored by the SRC to determine the candidates' potential to make a significant contribution to the cancer research program of the nominating institution. Review criteria focused on the overall impression of the candidate and his/her potential for continued superb performance as a cancer researcher, his/her scientific merit of the proposed research program, his/her long-term contribution to and impact on the field of cancer research, and strength of the institutional commitment to the candidate.

Questions that were considered by reviewers include: Has the candidate made significant, transformative, and sustained contributions to basic, translational, clinical or population-based cancer research? Is the candidate an established and nationally and/or internationally recognized leader in the

field? Has the candidate demonstrated excellence in leadership and teaching? Has the candidate provided mentorship, inspiration, and/or professional training opportunities to junior scientists and students? Does the candidate have a strong record of research funding? Does the candidate have a publication history in high-impact journals? Does the candidate show evidence of collaborative interaction with others?

Wei Yang, Ph.D., is an internationally known structural biologist and member of the National Academy of Sciences who is being recruited to the Department of Molecular Biosciences in the College of Natural Sciences at The University of Texas at Austin from National Institutes of Health, National Institutes of Diabetes and Digestive and Kidney Diseases. Dr. Yang has been a leader in three areas of molecular biology that relate to cancer: mismatch repair, DNA double-strand break repair, and error-prone DNA polymerases. Within each field she has set the bar for the highest achievements in structural biology, including solving the first structures of several classes of novel DNA repair enzymes. Recently, she pioneered the new field of enzyme catalysis within crystals, enabling real-time molecular movies of enzymatic reactions with DNA polymerases to visualize transition states for the first time. Dr. Yang plans an ambitious range of new projects at UT-Austin that will use cryo-electron microscopy, single-molecule fluorescent technologies, and small molecule screening to take her cancer-related interests to the next level

Recruitment of Rising Stars (RFA R-16-RRS)

Applications Reviewed: 1
Applications Recommended: 1

Total Funding Request: \$4,000,000

The aim of this RFA is to recruit outstanding early-stage investigators to Texas, who have demonstrated the promise for continued and enhanced contributions to the field of cancer research. Award: Up to \$4 million over a period of 5 years.

These applications were evaluated and scored by the SRC to determine the candidate's potential to make a significant contribution to the cancer research program of the nominating institution. Review criteria focused on the overall impression of the candidate and his/her potential for continued superb performance as a cancer researcher, his/her scientific merit of the proposed research program, his/her long-term contribution to and impact on the field of cancer research, and strength of the institutional commitment to the candidate.

Questions that were considered by reviewers include: Has the candidate demonstrated extraordinary accomplishments during his or her initial years of independent research? Does the candidate show promise of making important contributions with significant impact to basic, translational, clinical, or population-based cancer research in the future? Has the candidate demonstrated strong self-direction, motivation, and commitment for transformative cancer research?

Andrew D. Rhim, M.D., is being recruited from the University of Michigan, Department of Internal Medicine/Gastroenterology and Cancer Center to The University of Texas M.D. Anderson Cancer Center, Department of Gastroenterology in the Division of Internal Medicine. Dr. Rhim is an exceptional basic scientist that was selected among 19 outstanding candidates to receive this year's MDACC Physician Scientist Award based on the strength of his achievements and potential to be a leader in cancer research. He published paradigm-shifting first-author papers in Cell and Cancer Cell

and obtained highly competitive peer reviewed grants from NIH, Doris Duke Charitable Foundation, and American Academy of Cancer Research. In recognition of past and current research, Dr. Rhim was recognized with the 2014 Young Physician Scientist Award from the American Society of Clinical Investigation. Dr. Rhim is also an accomplished translational researcher, evidenced by multiple ongoing clinical trials of novel biomarkers of subclinical pancreatic cancer. Dr. Rhim's expertise will be utilized to establish the only high risk pancreatic cancer clinic in the State of Texas and to build a robust and innovative program focused on endogenous DNA and RNA editing in cancer. Dr. Rhim is an outstanding physician scientist who will bring enormous strength to the MDACC burgeoning clinical and basic research programs in pancreatic cancer.

Recruitment of First-Time, Tenure-Track Faculty Members (RFA R-16-RFT)

Applications Reviewed: 4
Applications Recommended: 3

Total Funding Request: \$6,000,000

The aim of this RFA is to recruit and support very promising emerging investigators, pursuing their first faculty appointment in Texas, who have the ability to make outstanding contributions to the field of cancer research. Award: Up to \$2 million over a period of 4 years.

The applications were evaluated and scored by the SRC to determine the candidates' potential to make a significant contribution to the cancer research program of the nominating institution. Review criteria focused on the overall impression of the candidate and his/her potential for continued superb performance as a cancer researcher, his/her scientific merit of the proposed research program, his/her long-term contribution to and impact on the field of cancer research, and strength of the institutional commitment to the candidate.

Questions that were considered by reviewers include: Has the candidate demonstrated academic excellence? Has the candidate received excellent predoctoral and postdoctoral training? Does the candidate show exceptional potential for achieving future impact on basic, translational, clinical, or population-based cancer research in the future? Has the candidate demonstrated a commitment to cancer research? Has the candidate demonstrated independence or the potential of independence?

Three First-Time, Tenure-Track Faculty Member Award candidates are being recommended for recruitment: one to The University of Texas Health Science Center at Houston, one to The University of Texas Health Science Center at San Antonio, and one The University of Texas M.D. Anderson Cancer Center. Listed below is the candidate with his associated expertise. Each has had outstanding training, an excellent record of achievement, and a strong commitment to cancer research.

- **Dung-fang Lee, Ph.D.**, (UTHSC-H) osteosarcoma, p53 systems biology, stem-cell biology, iPSC technology, Li-Fraumeni syndrome, genome editing, cell signaling, tumor supressor genes
- **Zhijie (Jason) Liu, Ph.D.**, (UTHSC-SA) breast cancer, estrogen receptor, transcription regulation, hormone resistance
- Nidhi Sahni, Ph.D., (UTMDA) Cancer Sys Biology, Molecular Genetics, Bioinformatics/Computational Biology, Interactive Networks, Cancer Therapeutics, Oncology Signaling Pathways, Proteomics, Coding/Non-Coding Genomic Variation





San Diego

Ludwig Institute for Cancer Research Ltd October 29, 2015

Richard D. Kolodner Ph.D.

Director, San Diego Branch

Head, Laboratory of Cancer Genetics San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

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UC San Diego School of Medicine CMM-East / Rm 3058 9500 Gilman Dr - MC 0669 La Jolla, CA 92093-0669

T 858 534 7804 **F** 858 534 7750

Mr. Pete Geren

Oversight Committee Presiding Officer Cancer Prevention and Research Institute of Texas Via email to pgcprit@sidrichardson.org

Mr. Wayne R. Roberts Chief Executive Officer Cancer Prevention and Research Institute of Texas Via email to wroberts@cprit.state.tx.us

Dear Mr. Geren and Mr. Roberts,

In reviewing the list of recommended applications, we were made aware of one minor error in scoring. Application RP160268 was assigned a score of 2.6 in the list, and the actual score should be 2.7. This recommended application was initially placed in row 41 and now appears in row 44. The change of score is reflected in the attached revised list. This does not change the outcome of the SRC recommendation.

Sincerely yours,

Richard D. Kolodner, Ph.D.

Chair, CPRIT Scientific Review Council



San Diego

Ludwig Institute for Cancer Research Ltd October 29, 2015

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Mr. Wayne R. Roberts Chief Executive Officer Cancer Prevention and Research Institute of Texas Via email to wroberts@cprit.state.tx.us

Dear Mr. Geren and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for the Individual Investigator Research Awards (IIRA), Individual Investigator Research Awards for Computational Biology (IIRACB), Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA), Individual Investigator Research Awards for Prevention and Early Detection (IIRAP), Research Training Awards (RTA), and Research Training Awards - Renewal (RTA-R) grant mechanisms. The SRC met on Friday, October 23, 2015 to consider the applications recommended by the peer review panels following their meetings that were held September 29 - October 7, 2015. During the SRC discussion, it was determined that the success rates (percentage of the number recommended/number reviewed) for four panels were much higher than the rates for the other three panels and higher than the historical approval rates. It was suggested that these four panels reduce their success rates to fall in line with the other panels, and all chairs agreed to the scoring adjustments. This resulted in some applications not being recommended for grant awards that received scores equal to or more favorable than some applications that were recommended for grant awards. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded after adjustments were made based on success rates.

Recommended funding amounts and the overall evaluation score are stated for each grant application. The SRC accepted the recommendations of the peer review panels concerning adjustments to three grant applications. These adjustments with justifications are listed at the end of the list of recommended projects. The total amount for the applications recommended is \$62,761,270.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.



San Diego

Sincerely yours,

Richard D. Kolodner, Ph.D.

Chair, CPRIT Scientific Review Council

Attachment

Rank	App ID	Organization/Company	Application Title	Award Amount	Mech.	Overall Score
Kank	App ID	* *		Amount		Score
	DD1 (0157	The University of Texas	Cancer Intervention and Prevention	Ф2 002 250	RTA-	1.0
1			Discoveries Program	\$3,993,250	Renewal	1.2
			Decoding Cellular Heterogeneity of			
2	RP160192	Baylor College of Medicine	Malignant Glioma	\$899,701	IIRA	1.3
			Protein Truncation Mutations in WIP1:			
3	RP160451	Baylor College of Medicine	Effects on Cancer and Hematopoiesis	\$900,000	IIRA	1.5
			Development of Therapeutics			
			Targeting Truncated Adenomatous			
			Polyposis Coli (APC) as a Novel			
		The University of Texas	Prevention and Intervention Strategy			
4	RP160180	Southwestern Medical Center	for Colorectal Cancer	\$900,000	IIRA	1.8
			A novel epigenetic reader as			
		The University of Texas M. D.	therapeutic target in MLL-translocated		IIRACC	
5*	RP160237	Anderson Cancer Center	pediatric leukemias	\$900,000	A	1.8
			Baylor College of Medicine			
			Comprehensive Cancer Training		RTA-	
6	RP160283	Baylor College of Medicine	Program	\$3,986,268	Renewal	1.9
		The University of Texas				
_		Health Science Center at San			IIRACC	
7	RP160487	Antonio	Cytokine signaling in Ewing sarcoma	\$1,200,000	A	1.9
			A Randomized Controlled Trial (RCT)			
			of Patient Navigation for Lung Cancer			
	DD1 60000	The University of Texas	Screening in an Urban Safety-Net	01.402 51 5	110 : 5	
8	RP160030	Southwestern Medical Center	System	\$1,492,616	IIRAP	1.9
			Promoting The Functions of Memory T			
9	RP160384	Baylor College of Medicine	cells for Adoptive T cell Therapy	\$887,676	IIRA	1.9
			Role of Long Non-Coding RNAs in			
			Breast Cancer: Identification,			
		The University of Texas	Characterization, and Determination of			
10	RP160318	Southwestern Medical Center	Molecular Functions	\$886,652	IIRA	2.0

LUDWIG CANCER RESEARCH

San Diego

		-	<u> </u>		,	
			Arylhydrocarbon receptor mediated			
11	RP160589	Texas AgriLife Research	modulation of colorectal cancer by microbiota metabolites	\$890,840	IIRAP	2.0
- 11	Ki 100307	Texas rigitalite Research	Pediatric Radiation Oncology with	\$670,040	IIIQ II	2.0
		The University of Texas	Movie Induced Sedation Effect		IIRACC	
12**	RP160190	Southwestern Medical Center	(PROMISE)	\$900,000	A	2.0
		The University of Texas M. D.	Amplified gold nanoparticle-mediated			
13	RP160497	Anderson Cancer Center	radiosensitization of tumors	\$899,309	IIRA	2.0
			Imaging-based quantitative analysis of			
		The University of Texas M. D.	vascular perfusion and tissue oxygenation to improve therapy of			
14	RP160229	Anderson Cancer Center	hepatocellular carcinoma	\$885,901	IIRA	2.0
- 1	100225	7 Hiderson Cancer Center	Molecular Mechanism of NLRP12-	ψουσ,συτ	mar	2.0
		The University of Texas	mediated Regulation of Colorectal			
15	RP160169	Southwestern Medical Center	Cancer	\$897,707	IIRA	2.1
		The University of Texas	DIS3L2 in Childhood Wilms Tumor:		IIRACC	
16***	RP160249	Southwestern Medical Center	Mechanism to Medicines	\$1,200,000	A	2.1
			Carbamoyl Phosphate Synthase-1: A			
17	DD160000	The University of Texas	new metabolic liability in non-small	\$000,000	IID A	2.1
17	RP160089	Southwestern Medical Center	cell lung cancers	\$900,000	IIRA	2.1
18	RP160501	The Methodist Hospital Research Institute	De-Orphanizing TLX: Implications for Glioblastomas	\$878,969	IIRA	2.1
10	KF 100301		Gilobiastollias	\$676,909	IIKA	2.1
19	RP160622	The University of Texas Southwestern Medical Center	Computational live cell histology	\$392,779	IIRACB	2.1
17	KI 100022	Southwestern Wedicar Center	Cancer Prevention Post-Graduate	\$392,119	IIKACD	2.1
			Training Program in Integrative			
20	RP160097	Baylor College of Medicine	Epidemiology	\$2,986,890	RTA	2.1
		The University of Texas	Collaborative Training of a New Cadre			
		Health Science Center at	of Innovative Cancer Prevention		RTA-	
21	RP160015	Houston	Researchers	\$4,000,000	Renewal	2.1
	22460	The University of Texas	The role of the Lats kinases in	#000 = 00	****	
22	RP160340	Southwestern Medical Center	sarcomatoid renal cell carcinoma	\$899,598	IIRA	2.2
			Exploiting molecular and metabolic			
22	DD1/0102	The University of Texas M. D.	dependencies to optimize personalized	¢000 000	IID A	2.2
23	RP160183	Anderson Cancer Center	therapeutic approaches for melanomas Understanding Biological and Physical	\$900,000	IIRA	2.2
			Factors Affecting Response to Proton			
		The University of Texas M. D.	Therapy to Improve its Clinical			
24	RP160232	Anderson Cancer Center	Effectiveness	\$879,362	IIRA	2.2
			Role of Cohesin in Hematopoiesis and			
			Myeloid Leukemia in Children with	.	IIRACC	
25	RP160022	Baylor College of Medicine	Down Syndrome	\$1,905,638	A	2.2
26	DD1/02/42	The University of Texas M. D.	Mechanisms and targeting strategies for	#000 000	IID 4	2.2
26	RP160242	Anderson Cancer Center	SWI/SNF mutations in cancer	\$900,000	IIRA	2.3
		The University of Texas	Targeting the undruggable: a first-in- class inhibitor of the HIF-2			
27	RP160440	Southwestern Medical Center	transcription factor	\$899,412	IIRA	2.3
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			Early Detection of Ovarian Cancer with			
		The University of Texas M. D.	Tumor Associated Proteins and			
28	RP160145	Anderson Cancer Center	Autoantibodies	\$1,497,595	IIRAP	2.3
		The University of Texas M. D.				
29	RP160013 Anderson Cancer Center Visualizing T-cell trafficking		Visualizing T-cell trafficking	\$900,000	IIRA	2.3
			An Adaptive Personalized Clinical	·		
			Trial using a Patient-Derived Xenograft			
		The University of Texas M. D.	Strategy to Overcome Ibrutinib			
30	RP160019	Anderson Cancer Center	Resistance in Mantle Cell Lymphoma	\$841,606	IIRA	2.3
				Í		
		Texas A&M University	Improving contrast for antibody-based			
31	RP160051	System Health Science Center	tumor detection using PET	\$887,134	IIRA	2.3
31	KI 100031	System Health Science Center	Investigating the genetic and molecular	Φ007,134	ША	2.3
		The University of Texas M. D.	mechanisms underlying RAS/ERK			
32	RP160023	Anderson Cancer Center	substrate network	\$900,000	IIRA	2.4
32	100023	1 macison cuncor contor	Novel tumorigenic mechanisms of the	Ψ200,000	шил	۵.٦
		The University of Texas	LKB1 tumor suppressor in endometrial			
33	RP160211	Southwestern Medical Center	and cervical cancer	\$896,653	IIRA	2.4
	10.100211	South Colon Modern Collect		\$0,0,000	111(1)	2.1
		The Hairmaide of CT and a	Role of PARP-1 in Estrogen Receptor			
2.4	DD160210	The University of Texas	Enhancer Function and Gene	¢004 215	IID A	2.4
34	RP160319	Southwestern Medical Center	Regulation Outcomes in Breast Cancers	\$884,315	IIRA	2.4
		The University of Texas	Chemoprevention of Colon Cancer by			
2.5	DD160124	Health Science Center at San	Anti-inflammatory Blockade Using	¢000 (17	IID A D	2.4
35	RP160124	Antonio	Neem	\$899,617	IIRAP	2.4
		The University of Texas M. D.	Regulation of infiltration and function	****		
36	RP160188	Anderson Cancer Center	of tumor-resident CD8 T cells by IL-15	\$828,060	IIRA	2.4
		The University of Texas	Structural and Functional Analyses of			
37	RP160255	Southwestern Medical Center	the Spindle Checkpoint	\$900,000	IIRA	2.5
		The University of Texas				
38	RP160307	Southwestern Medical Center	Targeting Metastatic Pathways	\$900,000	IIRA	2.5
			Exosomal DNA as a surrogate	·		
			biomarker for early diagnosis and			
	1	The University of Texas M. D.	therapeutic stratification in pancreatic			
39	RP160517	Anderson Cancer Center	cancer	\$891,938	IIRA	2.5
			Engineering T cells to ensure			
			specificity for tumor cells and their			
40	RP160345	Baylor College of Medicine	environment	\$900,000	IIRA	2.5
		The University of Texas M. D.	Nanoparticle Targeted STAT3 Immune			
41	RP160482	Anderson Cancer Center	Expression	\$888,429	IIRA	2.6
			Clinical Safety and Efficacy of Third	ŕ		
			party, fucosylated, cord blood derived			
		The University of Texas M. D.	regulatory T cells to prevent graft			
42	RP160121	Anderson Cancer Center	versus host disease	\$900,000	IIRA	2.6
		The University of Texas	Effect of Chest Radiation Therapy on	·		
43	RP160520	Southwestern Medical Center	Cardiomyocyte Turnover	\$897,570	IIRAP	2.6
	12230220	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	DNA damage-induced small non-	4227,070		
		The University of Texas	coding RNAs: mechanism and their			
44	RP160268	Southwestern Medical Center	role in cancer development	\$900,000	IIRA	2.7
		The state of the s		+,		

LUDWIG CANCER RESEARCH

San Diego

			Integrin-mediated IL-18 signaling in			
		The University of Texas	the prevention and treatment of			
		Health Science Center at San	inflammation-associated colorectal			
45	RP160512	Antonio	cancer	\$859,620	IIRA	2.7
			A novel function of Itch in controlling			
			IL-17-induced inflammation in colon			
46	RP160577	Baylor Research Institute	cancer	\$900,000	IIRA	2.7
			Optimizing therapeutic strategies			
		The University of Texas at	against lung cancer using Multi-			
47	RP160617	Dallas	Modality Imaging	\$899,999	IIRA	2.7
			Characterization and pharmacological	. ,		
		The University of Texas	targeting of the oncogenic activity of			
48	RP160493	Southwestern Medical Center	Jumonji enzymes	\$899,997	IIRA	2.8
			The CTC Circulator Phenotype:	*		
			Insights into Mechanisms of Breast			
49	RP160054	Daylor College of Medicine	Cancer Dormancy	¢004 222	IIRA	2.9
49	KP100034	Baylor College of Medicine The University of Texas		\$884,332	IIKA	2.9
		Health Science Center at	Regulation of tumor aggressiveness and			
50	DD1 (0225		immune suppression in lung	#000 000	IID A	2.0
50	RP160235	Houston	adenocarcinoma	\$900,000	IIRA	2.9
			Radiogenomic Screen to Identify Novel			
			Proliferation-associated Glioblastoma			
			Genomic Therapeutic Targets:			
-,	DD1 (0170	The University of Texas M. D.	Discovery and Mechanistic Validation	#00 7.637	IID 4	2.0
51	RP160150	Anderson Cancer Center	Study	\$897,627	IIRA	3.0
			High resolution imaging for early and			
52	RP160460	Rice University	better detection of bladder cancer	\$873,765	IIRAP	3.0
		The University of Texas M. D.	Identifying new epigenetic			
53	RP160471	Anderson Cancer Center	vulnerabilities in pancreatic cancer	\$900,000	IIRA	3.1
			Systematic identification of small	. , ,		
			molecule inhibitors that manipulate			
54	RP160462	Baylor College of Medicine	telomerase activities	\$898,288	IIRA	3.2
	=======	,	The role of Prdm16 and histone H3	+ = > = ,= = =		
			lysine 9 methyltransferase complex in			
55	RP160035	Baylor College of Medicine	MDS	\$872,157	IIRA	3.2

^{*}RP160237 - The peer review panel recommended reducing the budget to \$300,000 per year for 3 years for a total of \$900,000 based on the scope and depth of the work proposed.

^{**}RP160190 - The peer review panel recommended not funding Aim 4 (Pilot prospective clinical trial) and reducing the budget to \$300,000 per year for 3 years for a total of \$900,000. The final score was based on revised scope with full deletion of Aim 4.

^{***}RP160249 - The peer review panel recommended that given the absence of a clinical trial, the budget should be reduced to \$300,000 per year for 4 years for a total of \$1,200,000.



San Diego

Success Rate by Panel			
Peer Review	Success	Score	
Panel	Rate	Cutoff	
BCR1	10%	2.3	
BCR2	11%	3.2	
СВ	9%	3.2	
CPR	9%	2.4	
CTCR/TCR	13%	2.7	
ITI	11%	3.0	

Success Rate	Success Rate by Mechanism vs. Total Reviewed				
Mechanism	Success Rate	# Recommended			
IIRA	11%	39/347			
IIRACB	2%	1/50			
IIRACCA	11%	5/44			
IIRAP	13%	6/44			
RTA	14%	1/7			
RTA-R	50%	3/6			
Overall	11%	55/498			

Percent of Applications Recommended by			
Mechai	Mechanism vs. Total Reco		
Mechanism	# Recommended	Percentage	
IIRA	39/55	71%	
IIRACB	1/55	2%	
IIRACCA	5/55	9%	
IIRAP	6/55	11%	
RTA	1/55	2%	
RTA-R	3/55	5%	
Overall	55/55	100%	



San Diego

Ludwig Institute for Cancer Research Ltd October 26, 2015

Richard D. Kolodner Ph.D.

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Mr. Pete Geren
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to pgcprit@sidrichardson.org

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Mr. Geren and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit its list of recruitment grant recommendations. The SRC met on Monday, October 19, 2015 to consider the applications submitted to CPRIT under the **Recruitment of Established Investigator, Recruitment of Rising Stars, and Recruitment for First-Time, Tenure Track Faculty Members** Request for Applications for Recruitment Cycles REC 16.2 and 16.3. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. There were no changes to funding amounts, goals, timelines, or project objectives requested by other applicants. The total amount for the applications recommended is \$16,000,000.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, a commitment to cancer research, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.

Sincerely yours,

Richard D. Kolodner, Ph.D.

Chair, CPRIT Scientific Review Council

Attachment

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

Rank	App ID	Candidate	Organization/Company	Mech.	Budget Requested	Overall Score
			The University of Texas Health Science Center			
1	RR160019	Dung-fang Lee	at Houston	RFT	\$2,000,000	1.0
2	RR160020	Wei Yang	The University of Texas at Austin	REI	\$6,000,000	1.0
3	RR160022	Andrew D. Rhim	The University of Texas M. D. Anderson Cancer Center	RRS	\$4,000,000	1.8
4	RR160017	Zhijie Liu	The University of Texas Health Science Center at San Antonio	RFT	\$2,000,000	2.5
5	RR160021	Nidhi Sahni	The University of Texas M. D. Anderson Cancer Center	RFT	\$2,000,000	2.5

RFT = Recruitment of First-Time, Tenure-Track Faculty Members

REI = Recruitment of Established Investigators

RRS = Recruitment of Rising Stars

Prevention

Recommendation

Items

Prevention Awards Summary

Review Council Chairman Letter





CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: REBECCA GARCIA, PH.D., CHIEF PREVENTION AND COMMUNICATIONS

OFFICER

SUBJECT: PREVENTION GRANT RECOMMENDATIONS

DATE: NOVEMBER 3, 2015

Summary and Recommendation:

The Program Integration Committee has reviewed the rank ordered list of applications submitted by the CPRIT Prevention Review Council and recommends awarding 12 projects totaling \$13,247,742. The grant recommendations are presented in five slates corresponding to the following grant mechanisms:

- 1. Evidence-Based Cancer Prevention Services
- 2. Evidence-Based Cancer Prevention Services Colorectal Cancer Prevention Coalition
- 3. Competitive Continuation/Expansion for Evidence-Based Cancer Prevention Services
- 4. Cancer Prevention Promotion and Navigation to Clinical Services
- 5. Dissemination of CPRIT-Funded Cancer Control Interventions

Background:

Five RFAs were released April 30, 2015 and applications were due July 9, 2015. Twenty prevention grant applications were submitted in response to the following CPRIT RFAs. One application was administratively withdrawn and peer review of the remaining 19 applications was conducted in September.

- *Evidence-Based Cancer Prevention Services* For projects that provide the delivery of evidence-based prevention services (e.g., screening, survivorship services). The maximum grant award is up to \$1.5 million for up to three years.
- Colorectal Cancer Prevention Coalition -- For projects that will deliver a comprehensive and integrated colorectal cancer screening project that includes provision of screening, diagnostic, and navigation services in conjunction with outreach and education of the target population through a coalition of partners. No funding cap, up to three years.
- Competitive Continuation/Expansion for Evidence-Based Cancer Prevention Services For projects that propose to continue or expand highly successful projects previously or currently funded by CPRIT. The award ranges from \$150,000 to \$1.5 million up to three years, depending on the type of project proposed.
- Cancer Prevention Promotion and Navigation to Clinical Services—for projects that deliver public education and outreach and navigation to cancer screening and preventive services. Maximum of \$400,000; maximum duration of 36 months.
- **Dissemination of CPRIT-Funded Cancer Control Interventions-** to fund projects that will facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based

cancer prevention and control interventions across Texas. Maximum of \$300,000; maximum duration of 24 months.

All of the recommended applications address one or more of the Prevention Program priorities. Specifically, 3 of grants prioritize population and geographic areas of greatest need, 12 focus on underserved populations, and 5 focus on increased targeting of efforts to areas where significant disparities in the state exist.

Evidence-Based Cancer Prevention Services Slate

Recommended projects (3): \$4,079,529

Six applications were submitted in this mechanism. Three new evidence-based prevention services projects are recommended.

PP160042	Using Best Practices to	Parra-Medina,	The University of
	Promote HPV vaccination in	Deborah	Texas Health
	Rural Primary Care Settings		Science Center at
			San Antonio

Formative assessments will identify and understand factors that influence HPV vaccine practices of health care providers and HPV vaccine coverage in six South Texas Rural Health Services clinics that serve residents from four medically underserved rural counties (Dimmit, LaSalle, Frio and Medina). Immunization champions will be used to implement health care system based strategies such as clinic-based education and client reminders/recalls to enhance patient access to vaccine services. In addition the project will also integrate community-wide education (CE) and outreach to increase the HPV vaccine initiation and completion rates among youth by targeting health care professionals and the community.

PP160010	Maximizing opportunities for	Berenson, Abbey	The University of
	HPV vaccination in the	В	Texas Medical
	Golden Triangle		Branch at Galveston

The strategy to increase the number of adolescents and young adults vaccinated against HPV includes patient navigation services, vaccination at no cost to the patient, thorough patient tracking, reminder methods, and provider education. Multiple strategies to reach out to the entire community will be employed. In addition the project will educate regional providers in groups and individually to increase physician recommendation and vaccination rates for this vaccine throughout the community.

PP160027	Improving Service Delivery	Foxhall, Lewis E	The University of
	to Cancer Survivors in		Texas M. D.
	Primary Care Settings		Anderson Cancer
			Center

The setting is primary care training program clinical practices that care for underserved priority patient populations. The intervention utilizes a comprehensive approach to engage cancer

survivors, oncology specialists and the primary care clinical team. Practice system changes will be implemented to identify cancer survivors currently receiving general medical care in the practices. The clinicians will obtain or develop treatment summaries and survivorship care plans for those patients. Procedures will be implemented to promote communication with treating oncologists or cancer centers to coordinate delivery of survivorship care management to reduce duplication of effort and eliminate gaps in care. The knowledge base of primary care clinicians related to survivorship care management will be assessed and further online education materials and support programs will be offered as needed.

Colorectal Cancer Prevention Coalition

Recommended projects (1): \$2,299,753

One application was received in response to the colorectal cancer coalition RFA and is being recommended for funding.

PP160023	Optimizing Colorectal Cancer	Sauter, Edward	The University of
	Screening in East Texas		Texas Health Center
			at Tyler

The project will provide a coordinated program to increase access to and delivery of colorectal cancer (CRC) services to individuals in a 19 county area of East Texas. The program leverages a complementary, non-overlapping partnership with a federal program, focusing on the uninsured and underinsured. Multiple partnerships with existing community programs which people in this region trust have been established. The project will engage clinical colleagues in primary care who deliver medical services to many thousands of individuals in this region to assist with recruitment to the program. Through a partnership with the American Cancer Society (ACS) the program will provide CRC screening education to clinical partners, community health workers, and to eligible participants.

Competitive Continuation/Expansion Grants

Recommended projects (4): \$5,488,991

This mechanism is intended to fund the continuation or expansion of currently or previously funded projects that have demonstrated exemplary success as evidenced by progress reports and project evaluations. Of the six applications submitted, four are being recommended for funding.

PP160049	Expansion of a comprehensive cervical cancer screening program	Anderson, Matthew L	Baylor College of Medicine
	for medically underserved women in Harris County		

This project will expand successful navigation efforts to improve and streamline the referral of women diagnosed with cytology at sites external to the Harris Health System (HHS). The focus

of the navigation platform will be expanded with engaging the large population of Hispanic and African American women who have never been previously screened for cervical cancer despite the fact that they are actively receiving other types of primary care at an HHS facility. The streamlined navigation system is expected to navigate more than 13,500 women to timely screening and/or follow up.

PP160011	GRACIAS Texas: Genetic	Tomlinson, Gail	The University of
	Risk Assessment for Cancer		Texas Health
	in All South Texas		Science Center at
			San Antonio

This project will continue and expand to cover a broader area in southernmost region of Texas, including 23 additional underserved counties and provide the cancer genetic services, thus reaching underserved and indigent patients throughout South Texas where previously no cancer genetic counseling services existed. Two additional video teleconferencing (vtel) sites along the border that can provide access to cancer genetic counseling will be added in addition to genetic counseling by telephone in selected individuals from rural areas. Members of families with a significant family history of cancer will be offered cancer screening services. The project will train mammography technicians in family history taking in additional centers and the next generation of physician providers in South Texas by partnering with a new medical school in the Rio Grande Valley.

PP160047	A community based program	Savas, Lara	The University of
	to increase breast and cervical		Texas Health
	cancer screening and HPV		Science Center at
	vaccination to reduce the		Houston
	impact of breast and cervical		
	cancer among Latinas		

This project is an expansion and enhancement of program components that increase reach and implementation efficiencies. Guided by process and final evaluation results from the previous program, to increase reach, participation and to serve more women, the project will (1) modify education materials (2) create an alternative telephone-based education option (3) facilitate delivery of one-on-one navigation intervention with a more automated Navigation Tracking Tool, and (4) remove financial barriers for under or uninsured women ineligible for existing assistance programs. To increase program geographic expansion the project will train CHWs through a network of community CHW programs located on the South Gulf Coast of Texas.

PP160036	Establishing a Comprehensive	Sun, Helen	Light and Salt
	Cancer Prevention and		Association
	Support Program within		
	Asian American Communities		
	in Houston and Austin Areas		
	of Texas		

The proposed project is a joint effort of 12 Asian American (AA) community-based organizations, clinics and universities targeting Vietnamese, Chinese, Filipino and Korean

communities in Houston and Austin areas. Its four major components include: prevention/ education; screening; survivorship services; and capacity building. The cancer prevention and screening components address colon, breast, cervical and liver cancer, and healthy eating. Methods of service delivery include: seminars, workshops, health fairs, newspaper articles, and TV programs, one-on-one education, and curriculum-based nutrition classes. The screening services include mammogram, Hepatitis B and C, FOBT, and Pap Smear/HPV tests. The survivorship program provides group-based interventions, patient navigation, and one-on-one support for cancer patients.

Cancer Prevention Promotion and Navigation to Clinical Services

Recommended projects (2): \$779,691

Five applications were submitted to this mechanism (one was withdrawn); two are being recommended for funding.

PP160032	Family Health History-based	Chen, Lei-Shih	Texas A&M
	Colorectal Cancer Prevention		University
	and Navigation to Clinical		-
	Services among Uninsured		
	Chinese Americans in Texas		

In collaboration with three Asian American community organizations the program will provide colorectal cancer (CRC) prevention education, Family Health History (FHH) instruction, an FHH collection and tailored prevention messages tool, health insurance enrollment, and assistance navigating clinical services. The impact of the FHH-based program upon participants' behaviors (i.e., collecting FHH from family members, visiting doctors' offices for discussing FHH, adopting healthier lifestyles in diet, physical activity, alcohol and tobacco use, and adhering to personalized CRC screening recommendations) and theoretical mediators shaping such behaviors (i.e., knowledge, attitudes, self-efficacy, barrier, and intention) will be evaluated by pre-test, 6-, and 12-months post-intervention surveys.

PP160056	REACH Rural Education and	Hoelscher, Bill	Coastal Bend
	Awareness for Community		Wellness Foundation
	Health		

REACH will integrate community health worker program models to deliver targeted outreach, evidence-based education, and navigation to breast and cervical cancer screening and early detection services. The project will facilitate improvements in health status and quality of life. REACH will employ members of target population that share the same social, cultural, and economic characteristics to identify the target population and use culturally appropriate evidence-based education to facilitate health promotion. REACH will provide navigation support services to assist in linkage, transportation, and completion of breast and cervical cancer prevention screenings.

Dissemination of CPRIT-Funded Cancer Control Interventions

Recommended projects (2): \$599,778

Two applications were submitted to this mechanism and both are being recommended for funding.

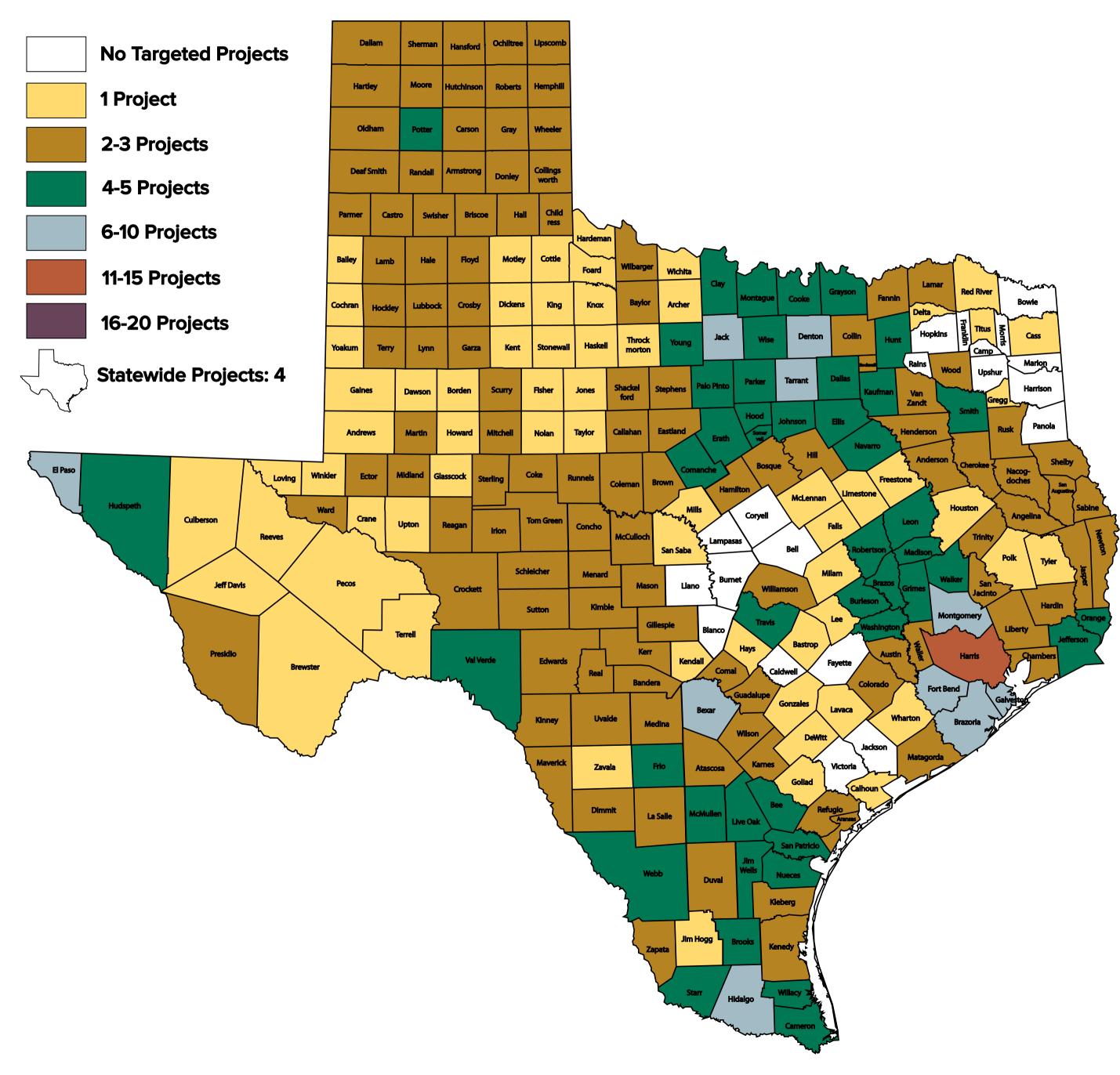
PP160048	Training CHWs for More	Bolin, Jane N	Texas A&M
	Effective Cancer Education		University System
	and Navigation		Health Science
	-		Center

Texas A&M Health Science Center will package and disseminate Community Health Worker (CHW) components from four of its successful CPRIT-funded prevention projects related to breast, cervical, and colorectal cancer (CRC) education, navigation, and outreach. CHWs in the priority regions will have access to certified training via in-person training workshops and CHWs across the state will be able to access online training modules. Organizations with CHW programs in the priority regions will be identified as partner organizations. Through in-person training, online resources, and ongoing technical assistance, this project will equip these partner programs to implement successful cancer education and navigation programs of their own.

PP160051	Dissemination of an Evidence-	Fernandez, Maria E	The University of
	Based HPV Vaccination		Texas Health
	Intervention in Community		Science Center at
	and Clinical Settings		Houston

With a CPRIT Research grant, two interventions designed to educate and to motivate Hispanic parents to vaccinate their children were developed and evaluated. This project will increase use of this program in both clinical and community settings to enhance the overall impact of the program on HPV vaccination rates across Texas. During Phase 1 (targeted dissemination for adopting agencies), the project will provide training and technical assistance for clinics and Community Health Worker (CHW) associations that have already expressed interest in implementing the *Por Nuestro Hijos* program. During Phase 2 (dissemination of PNH through clinical and community networks), the project will work closely with the Texas Department of State Health Services Breast and Cervical Cancer Services Program (BCCS) and CHW programs to increase awareness about PNH, garner interest, identify additional potential adopting clinics and CHW organizations and assess organizational readiness. Newly identified adopting clinics and organizations will then receive training and technical assistance.

COUNTIES SERVED BY CPRIT PREVENTION PROJECTS ACTIVE PROJECTS & PROPOSED AWARDS - NOVEMBER 2015



Pete Geren
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to pgcprit@sidrichardson.org

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Mr. Roberts and Mr. Geren,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for CPRIT Prevention grant awards. The applicants on the attached list of submitted proposals responded to CPRIT requests for applications (RFA) released for the first review cycle of FY2016. These recommendations reflect 50+ hours of work by individual reviewers and include panel discussion of the applicants' proposals, in addition to the PRC's programmatic review.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are provided for each grant application. The PRC did not make changes to the goals, timelines, or project objectives requested by the applicants. When the PRC did not follow the rank ordered scores in developing its recommended funding order a justification, based upon established programmatic priorities outlined in the RFAs, is provided.

The projected funding available for this fiscal year is \$27,965,885. However, the recent interpretation that annual prevention program funding is 10% of the CPRIT awarded dollars within a fiscal year could impact the dollars available. With the second funding cycle for the fiscal year underway, the PRC opted for a conservative approach to its recommendations for this cycle. Recommendations are provided at two levels: (1) initially fund 12 projects totaling an estimated \$13,247,742 and (2) depending upon the availability of funds later in the fiscal year, fund an additional 2 projects (PP160046 and PP160033 totaling \$2,999,657).

Our recommendations meet the PRC's standards for grant award funding of projects that are evidence-based, deliver programs or services to underserved populations, and focus on primary, secondary or tertiary prevention. In making these recommendations the PRC also considered the available funding, the composition of the current portfolio, and the programmatic priorities in the RFA which include potential for impact and return on investment, geographic distribution, cancer type and type of program. All of the recommended grants address one or more of the Prevention Program priorities.

Sincerely,

Stephen W. Wyatt, DMD, MPH Chair, CPRIT Prevention Review Council

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP160049	CCE- EBP	Expansion of a comprehensive cervical cancer screening program for medically underserved women in Harris County	Anderson, Matthew L	Baylor College of Medicine	\$1,500,000	1.9			1	
PP160047	CCE- EBP	A community based program to increase breast and cervical cancer screening and HPV vaccination to reduce the impact of breast and certical cancer among Latinas	Savas, Lara S	The University of Texas Health Science Center at Houston	\$1,387,005	2.7	Steps that will be taken to assess actual # of screenings and vaccinations for participants in educational sessions are not explained. It appears that only women completing the surveys will be followed. Evaluation of outcomes for all participants is not provided, only provided for women completing surveys. Budget is unclear about number of screenings that will be paid for; number of financially supported	Changes not recommended-PRC reviewed peer review comments and determined those comments did NOT impact decision to recommend or impact rank order	2	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							screening isn't clearly stated.			
PP160042	EBP	Using Best Practices to Promote HPV vaccination in Rural Primary Care Settings	Parra- Medina, Deborah	The University of Texas Health Science Center at San Antonio	\$1,295,493	2.8	Outcomes evaluation doesn't have baseline and % increase noted. A highly intensive program is being implemented and the high cost is a barrier. If the cost is reduced, the applicability of the proposed approach may be enhanced. Reviewers would like the applicants to clarify why the increase in the budget from the previous grant to this grant. Why has the per person	changes not recommended- PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	3	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							cost increased so much?			
PP160032	PN	Family Health History-based Colorectal Cancer Prevention and Navigation to Clinical Services among Uninsured Chinese Americans in Texas	Chen, Lei- Shih	Texas A&M University	\$399,993	3.0	Findings from this study should be applied to follow-up treatment for the participants. Plans for this are lacking and should be provided.	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	4	
PP160056	PN	REACH Rural Education and Awareness for Community Health	Hoelscher, Bill	Coastal Bend Wellness Foundatio n	\$379,698	3.0	Should be clarified that \$25 gift card is not being offered to change the behavior of the participants.	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	5	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP160010	ЕВР	Maximizing opportunities for HPV vaccination in the Golden Triangle	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	\$1,409,909	3.1	Ask applicants why they do not plan to vaccinate young adults on college campuses. In addition, students could be used to help with recruitment	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	6	
PP160048	DI	Training CHWs for More Effective Cancer Education and Navigation	Bolin, Jane N	Texas A&M University System Health Science Center	\$300,000	3.1			7	
PP160023	EBP- CRC	Optimizing Colorectal Cancer Screening in East Texas	Sauter, Edward	The University of Texas Health Center at Tyler	\$2,299,753	3.3	Recommendation was made in previous application that providing FIT isn't evidence-based for people who are at significant risk for CRC; this isn't consistent with ACS guidelines. Ask how they came up with \$275/colonoscopy	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	8	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP160036	CCE- EBP	Establishing a Comprehensiv e Cancer Prevention and Support Program within Asian American Communities in Houston and Austin Areas of Texas	Sun, Helen	Light and Salt Associatio n	\$1,101,986	3.3	Request that the applicant provides a leadership plan that includes input from the three communities being targeted: Vietnames, Korean, and Filipino	changes not recommended-PRC reveiwed peer review comments and determined they did not impact decision to recommend or impact rank order	9	
PP160027	EBP	Improving Service Delivery to Cancer Survivors in Primary Care Settings	Foxhall, Lewis E	The University of Texas M. D. Anderson Cancer Center	\$1,374,127	3.5	Not clear how project will add to what is already happening in clinic. This is a large, complex project and not clear how it will be managed on a daily basis. Budget is weak and justification for some of the positions is lacking	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	10	Recommende d out of score order above one with higher score due to ROI and cancer type
PP160051	DI	Dissemination of an Evidence- Based HPV Vaccination Intervention in Community and Clinical Settings	Fernandez , Maria E	The University of Texas Health Science Center at Houston	\$299,778	3.6	List of current awards doesn't specify PD participation; it should be verified that PD isn't overcommitted. Budget seems somewhat personnel heavy and accounts for a	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	11	Recommende d out of score order above one with higher score due to type of program

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							large majority of voerall costs; careful review of personnel and their exact roles and responsibilities and whether or not any of the services are duplicative may be warranted.			
PP160011	CCE- EBP	GRACIAS Texas: Genetic Risk Assessment for Cancer in All South Texas	Tomlinson , Gail E	The University of Texas Health Science Center at San Antonio	\$1,500,000	2.7			12	Recommende d but ranked out of score order due to 1) ROI may be limited; large numbers need to be screened to identify at risk pop.
PP160046	EBP	Using social marketing and mobile school-based vaccination clinics to increase HPV vaccination uptake in highrisk geographic areas	Cuccaro, Paula	The University of Texas Health Science Center at Houston	\$1,499,668	2.2			13	Recommende d but out of score order due to 1) geography- several HPV grants in Harris county, 2) ROI-costs for education vs services

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP160033	CCE- EBP	Increasing cancer control behaviors among the underserved: A collaboration with Texas 2-1-1 programs	Fernandez , Maria E	The University of Texas Health Science Center at Houston	\$1,499,989	2.4			14	Recommende d but out of score order due to 1) geography- several HPV grants in Harris county, 2) cancer type- availabilty of breast and cervical services 3) ROI-costs for
										education vs services
				Initial funding (Rank #1- 12)	\$13,247,74 2					
				(Rank #13+14) 2nd	\$2,999,657					
				funding	9					

Product Development

Recommendation

Items

Product Development Awards Summary

Review Council Chairman Letter

Advance Funds Request





MEMORANDUM

To: MEMBERS OF THE OVERSIGHT COMMITTEE

From: MICHAEL LANG, CHIEF PRODUCT DEVELOPMENT OFFICER

Subject: PRODUCT DEVELOPMENT GRANT RECOMMENDATION

Date: NOVEMBER 3, 2015

Summary of Recommendation:

The Program Integration Committee (PIC) met on November 3, 2015, and unanimously recommends that the Oversight Committee approve a \$20,000,000 New Company product development research grant award to Ruga Corporation (Ruga), subject to certain contingencies and additional goals and objectives recommended by the Product Development Review Counsel (PDRC) and the PIC. The PIC's decision is consistent with the PDRC's recommendation conveyed by PDRC Chair Dr. Jack Geltosky to the chairs of the PIC and the Oversight Committee on October 26.

The scientific rationale underlying Ruga's proposed product development research project is highly rated by the review panel, receiving an overall score of 2.2. The project as proposed provides a more effective therapeutic option to treat acute myeloid leukemia and other aggressive cancers, including ovarian, endometrial, breast, renal and pancreatic.

In making the recommendation, the PDRC considered the company's potential to: 1.) expedite innovation and product development in cancer research and treatments; 2.) create and expand the number of high-quality new jobs in Texas; and 3.) make a return on CPRIT's investment in cancer research.

Background - FY 15.4 Review Cycle:

The RFAs for the FY 2015.4 review cycle were released January 5, 2015. All applications were submitted by February 9, 2015. Peer review took place at meetings on March 26, 2015 (peer review panel conference call), April 27-28, 2015 (in-person presentations), and October 12, 2015 (due diligence review).

CPRIT received 16 applications for the FY 2015.4 review cycle. Ten applicants were invited to make in-person presentations; of those that were presented, three were moved forward to due diligence review. After consideration of the due diligence reports, the PDRC recommended one grant application, Ruga, for a grant award. As noted by Dr. Geltosky's letter, the recommendation to fund Ruga reflects 50+ hours of individual review and panel discussion of the applicant's proposal as well as the PDRC's review of the due diligence reports for Ruga.

Mechanism of Support and Program Objectives:

Ruga is being recommended for a New Company Product Development research award. The award mechanism supports the work of new companies that intend to undertake product research and development in Texas with Texas-based employees. In determining eligibility for this award, CPRIT carefully evaluates whether applicants will have a significant presence in Texas. New Company Product Development Awards assist early-stage startup companies by providing the opportunity: (1) to further the research and development of new products for the diagnosis, treatment, supportive care, or prevention of cancer; (2) to establish infrastructure that is critical to the development of a robust industry; and (3) to fill any treatment, industry, or research gaps.

Consistent with CPRIT's Product Development Program Priorities, the New Company mechanism funds projects at companies that are most likely to bring important cancer care products to the market. Development of the therapeutic to treat acute myelogenous leukemia aligns with CPRIT's focus on rare and pediatric cancers and those of significant unmet clinical need.

Proposed New Company Product Development Award – Recommended by the Product Development Review Council

Ruga Corporation - \$20,000,000 New Company Product Development Research Award recommendation

Summary:

The \$20,000,000 award to Ruga supports the continued development of Ruga-S6, a therapeutic targeting certain aggressive, hard to treat cases of acute myeloid leukemia (AML). The funded project will advance the AXL/GAS6 inhibitor program through completion of Phase 1 clinical studies in hematological indications with a focus on adult AML, and potentially pediatric AML as well as certain advance solid tumors (*e.g.* ovarian, endometrial, renal, and pancreatic cancers.) Grant funds will support manufacturing activities, including cell line development, assay development, process development and scale-up, and production of cGMP material. Preclinical development will include additional pharmacokinetics, toxicology, immunogenicity, and biomarker studies. During the course of this project, Ruga will file an Investigational New Drug ("IND") application with the FDA and initiate Phase 1/2 Clinical studies, which will include both single and multiple-ascending dose studies in AML.

AML and Ruga-S6

AML is a cancer that begins in bone marrow and affects cells intended to mature into different types of blood cells. Approximately 18,860 new cases of AML were diagnosed in the U.S. in 2014. Ruga's therapy targets a specific genetic mutation evident in 20% – 25% of AML cases, FMS-related tyrosine kinase 3, ("FLT3"); most of these mutations are internal tandem duplications ("ITD"). Scientists report that AML cases that are FLT3-ITD positive are more aggressive and patients are significantly more likely to relapse. FLT3-ITD positive patients treated with the standard AML therapy protocol have a median survival of less than one year, and less than five percent are cured.

FLT3-ITD positive cases of AML are characterized by the binding together of a specific protein and ligand pair. Laboratory and animal experiments show that preventing the protein, known as AXL, and the GAS6 ligand from binding together will stop the progression of AML

Building upon these discoveries, Ruga developed Ruga-S6, which works as a decoy to bind to GAS6 so that GAS6 does not bind to the actual AXL receptor. Not all AML cases have this

AXL-GAS6 complication, so Ruga has also developed a proprietary blood-based companion diagnostic that may better identify patients that will benefit from the for Ruga-S6 treatment.

According to Ruga, other companies are currently developing treatments to address this issue, however, the treatments are more toxic and have a low response rates. This means that not only are the alternative treatments less effective, but it increases the patient's likelihood of developing resistance to other AML treatments. Ruga's approach addresses these critical issues.

The scientific rationale underlying Ruga's proposed product development research project is highly rated by the review panel, receiving an overall score of 2.2. The project as proposed provides a more effective therapeutic option to AML and other aggressive cancers, including ovarian, endometrial, breast, renal and pancreatic. By advancing Ruga-S6 through preclinical and clinical testing, Ruga aims provide a more effective therapeutic option for AML and other aggressive cancers, including ovarian, endometrial, breast, renal and pancreatic.

Ruga-S6 has the opportunity to seek FDA Orphan drug and Breakthrough status. The development of Ruga-S6 aligns with CPRIT's focus on rare and pediatric cancers and those of significant unmet clinical need. If funded, Ruga will fully relocate to Texas, where it will continue the development of Ruga-S6 in partnership with Texas-based institutions, including the Texas Medical Center.

Selected Reviewer Comments:

- "The approach used is innovative as it consists of using an engineered AXL Fx construct as a decoy receptor that acts as an antagonist to the receptor to its ligand Gas6. If successful, the outcome could substantially impact the treatment of AML as it would provide a new treatment approach."
- "Beautifully written application; clear articulation of the scientific rationale, preliminary data and plans for further preclinical and clinical development."
- "If it were to show efficacy in the clinic, it will be a significant new product against AML and potentially solid tumors as well. In particular, it may be useful in combination therapies to delay resistance to other therapies."

Funding Request and Risk Mitigation

Ruga is seeking a total of \$20 million from CPRIT if it achieves all project goals and objectives. Combined with the company's \$10 million in matching funds, Ruga intends to advance of the

GAS6/AXL inhibitor program from late preclinical (IND-enabling studies) through early proof of concept studies (Phase 1/2) in AML and in certain aggressive solid tumors. Ruga estimates filing its IND by Q1, FY2017.

Investing in early stage translational cancer research is inherently risky. Therapies that show promise in the lab and in animals may not make a measurable difference in humans or the treatment's side effects may be so severe as to not justify the benefits. Along with the increased risk of scientific failure, human studies are more expensive than laboratory and animal studies. CPRIT addresses the risk associated with larger product development awards by tying disbursement of grant funds to achieving specific goals and objectives. The company only receives the entire amount of the award if all goals and objectives are met. Because goals are usually associated with project milestones, such as receiving FDA approval for an investigational new drug (IND) filing or completing a Phase I clinical trial, achieving all goals also means that the project is making meaningful progress on the way to becoming a treatment option.

A summary of Ruga's goals and objectives, along with the associated tranches, are set forth below. (For a complete explanation of each goal and summary, please see pages 8 – 11 of the Ruga application.) In addition, the PDRC recommends the certain contingencies, goals, and objectives be included in the grant award contract. The PDRC's recommended goals and objectives and rationale are reflected in red and are in addition to those already specified Ruga's application. The PIC also recommends an additional objective be included in the contract. The additional objective is related to the proposed companion diagnostic and is reflected in blue. With the Oversight Committee's approval, these goals and objectives will be incorporated into the "Scope of Work" for the award contract.

Ruga's Project Goals and Objectives:

Prior to contract execution but no later than May 1, 2016:

 Ruga's licensing agreement with Stanford must be renegotiated. Unless CPRIT approves additional time, Ruga should provide the renegotiated license agreement to CPRIT by May 1, 2016.

Ruga's current license agreement mandates a substantial return to Stanford (15% of all payments and milestones payments). Although CPRIT's investment in the project is significant, it is a small amount of the total capital necessary to bring the proposed therapy to patients. It is the PDRC's opinion that if the onerous license terms remain in place, it will significantly affect Ruga's ability to raise necessary follow-on funding from investors. In addition, march-in rights included in the Stanford agreement place the company at risk of losing control of the project,

another issue that will make prospective funders unwilling to participate in future fundraising rounds. Unless the Stanford agreement is renegotiated, CPRIT should not disburse any grant funds to the company.

CPRIT's Chief Product Development Officer, with the input of the PDRC if necessary, should review the renegotiated license and advise the CPRIT CEO regarding whether to execute the contract.

Ruga should provide a copy of the agreement with Fuji Diosynth Biotech of Texas
(FDBT) to CPRIT and follow recommendations, if any, regarding renegotiation. Should
renegotiation of the FDBT agreement be necessary, it should be completed by May 1,
2016. Unless CPRIT approves additional time, Ruga should provide the renegotiated
agreement to CPRIT by May 1, 2016.

The PDRC is concerned that Ruga's agreement with FDBT may make the vector and expression system proprietary to the manufacturer with the reagents royalty-bearing. If this is the case, then Ruga must renegotiate the agreement before any grant funds are disbursed to the company to ensure that potential investors are not disincentivized. CPRIT's Chief Product Development Officer, with the input of the PDRC if necessary, should review the FDBT agreement and advise the CPRIT CEO regarding whether to execute the contract.

If Ruga successfully completes the pre-contract objectives, specific Goals and Objectives, summarized below, will be included in the executed grant contract:

Year 1 Tranche \$5,063,100

Establish Texas as the corporate headquarters for Ruga and specifically, the Texas Medical Center (TMC) as the hub for all advanced preclinical and clinical development activities for Ruga-S6. Relocating key personnel and creating new high-quality, professional jobs that are required to fully support the company's current and future operations in Texas. Develop strategic partnerships and initiate activities with Texas-based subcontractors and consultants that can provide the expertise, services, and infrastructure needed to accomplish the preclinical and clinical development of Ruga's products.

Year 1 Objectives

1. Initiate cell line development/engineering and process development activities with a selected contract manufacturing organization (CMO), FujiFilm Diosynth Biotechnologies Texas (FDBT), to perform all development and manufacturing activities for Ruga-S6. Key objectives of this phase of the project include identification, selection, and optimization of a high-expressing cell line suitable for further development of a robust, scalable, and current Good Manufacturing Practices (cGMP)-compliant process for

production of Ruga-S6. By the end of Year 1, FDBT will have completed cell line development, completed development of a Master Cell Bank (MCB), and produced sufficient material under non-cGMP to enable completion of GLP toxicology studies with Ruga-S6. Achieve production of their construct and formulation of the final recombinant decoy receptor Ruga plans to develop with FDBT.

The PDRC notes that the company's proposed timeline for the IND timeline may be optimistic. Therefore, the PDRC recommends that as part of the Project Year 1 tranche Ruga achieves production of their construct and formulation of the final recombinant decoy receptor they are planning to develop with FDBT. This will prepare the company for its discussions with the FDA and planned IND submission, so as to receive the FDA's concurrence of Ruga's plan.

The PDRC will approve achievement of this objective as part of CPRIT's tranche report approval process.

- 2. Perform IND enabling preclinical studies, including PK, PD, and biomarker studies.
- 3. Demonstrate successful development of the companion diagnostic test including showing sensitivity and specificity sufficient to guide use of the company's novel therapeutic compound.
- 4. Conduct a pre-IND meeting with the FDA.
- 5. Establish Ruga headquarters and operations in Texas; specifically, the Texas Medical Center (TMC) as the hub for all advanced preclinical and clinical development activities for Ruga-S6. This will be accomplished with the first six months of the Project Year1. Key positions that will be recruited for include a full-time outward-facing CEO who is responsible for strategy and engaging with strategic partners, including potential investors and regulatory professionals, a Chief Medical Officer with a regulatory background and a demonstrated history of product(s) approval, Director of Manufacturing, and Vice President of Clinical and Regulatory Affairs, and a Program Manager to manage the development program and the consultants; in addition to administrative and other professional staff. Consultants with specialized expertise in Chemistry, Manufacturing, and Controls (CMC) for fusion proteins, preclinical, and regulatory affairs will also be retained by the company within the first year of award.

The PDRC's strong recommendation of the proposed project is tempered by its concern regarding the ability of Ruga's current management to professionally manage the project. While the "virtual structure" approach outlined by the company is generally acceptable, the company's reliance upon contracted research personnel and the ability of the current CEO to devote time and expertise to steering the project through the FDA approval process raise questions that should be quickly addressed by the company. The company needs full-time

executive leadership as well as some key hires with regulatory approval expertise to interface with the contracted research personnel.

The PDRC will approve achievement of this objective as part of CPRIT's tranche report approval process. Ruga may consult with the Chief Product Development Officer prior to making final offers.

Year 2 Tranche \$10,513,000

Complete advanced preclinical and initiate clinical development activities required to seek approval for Ruga-S6 as a new biological drug from the FDA. Address the critical need for improved treatment options by translating Ruga-S6 into the clinic for evaluation of safety and efficacy to treat adults with AML, and specifically patient populations with genetic mutations known to contribute to more aggressive disease phenotypes (i.e. FTL3-ITD(+)), in addition to other aggressive solid tumor indications with significant unmet clinical need. Accelerate the development and availability of Ruga-S6 to these patients by optimizing clinical trial designs to enable Orphan drug and/or accelerated/Breakthrough designation with the FDA.

Year 2 Objectives

- 1. Complete GLP-toxicology study in Non-human primates.
- 2. Perform cGMP manufacturing to generate Ruga-S6 final drug product at 2,000L scale.
- 3. File IND application with the FDA.
- 4. Initiate Phase 1a clinical studies in adult patients with AML-FLT3(+).

Year 3 Tranche \$4,423,900

Advance clinical evaluation of Ruga-S6 in adult patients with AML, and in particular AML-FLT3(+) and expand Ruga-S6 product development platform to pediatric AML as well as other cancer indications through performance of Phase 1b/2a studies in solid tumor types, such as ovarian, renal, and pancreatic cancers.

Year 3 Objectives

- 1. Complete Phase 1a clinical studies and identify expansion cohorts for Phase 1b/2a study in adult patients with AML-FLT3 subtypes.
- 2. Initiate Phase 1b/2a studies for Solid Tumor(s).

October 26, 2015

Via email to Wayne R. Roberts (<u>wroberts@cprit.state.tx.us</u>) and Pete Geren (<u>pgcprit@sidrichardson.org</u>).

Dear Pete and Wayne,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's product development research grant awards. The PDRC recommends that the Program Integration Committee and the Oversight Committee approve a \$20,000,000 product development research grant award to Ruga Corporation (Ruga), subject to certain contingencies and additional goals and objectives recommended by the PDRC as outlined below.

This recommendation reflects 50+ hours of individual review and panel discussion of the applicant's proposal as well as the PDRC's review of the due diligence reports. Our recommendation meets the PDRC's standards for grant award funding. These standards include the company's potential to: 1.) expedite innovation and product development in cancer research and treatments; 2.) create and expand the number of high-quality new jobs in Texas; and 3.) make a return on CPRIT's investment in cancer research.

The scientific rationale underlying Ruga's proposed product development research project is highly rated by the review panel, receiving an overall score of 2.2. The project as proposed may provide a more effective therapeutic option to acute myeloid leukemia and other aggressive cancers, including ovarian, endometrial, breast, renal and pancreatic.

The PDRC recommends the following contingencies, goals, and objectives be included in the grant award contract. The goals and objectives are in addition to those already specified by Ruga in its application.

Prior to contract execution but no later than May 1, 2016:

 Ruga's licensing agreement with Stanford must be renegotiated. Unless CPRIT approves additional time, Ruga should provide the renegotiated license agreement to CPRIT by May 1, 2016.

Ruga's current license agreement mandates a substantial return to Stanford (15% of all payments and milestones payments). Although CPRIT's investment in the project is significant, it is a small amount of the total capital necessary to bring the proposed therapy to patients. It is the PDRC's opinion that if the onerous license terms remain in place, it will significantly affect Ruga's ability to raise necessary follow-on funding from investors. In addition, march-in rights included in the Stanford agreement place the company at risk of losing control of the project, another issue that will make prospective

funders unwilling to participate in future fundraising rounds. Unless the Stanford agreement is renegotiated, CPRIT should not disburse any grant funds to the company.

CPRIT's Chief Product Development Officer, with the input of the PDRC if necessary, should review the renegotiated license and advise the CPRIT CEO regarding whether to execute the contract.

 Ruga should provide a copy of the agreement with Fuji Diosynth Biotech of Texas (FDBT) to CPRIT and follow recommendations, if any, regarding renegotiation. Should renegotiation of the FDBT agreement be necessary, it should be completed by May 1, 2016. Unless CPRIT approves additional time, Ruga should provide the renegotiated agreement to CPRIT by May 1, 2016.

The PDRC is concerned that Ruga's agreement with FDBT may make the vector and expression system proprietary to the manufacturer with the reagents royalty-bearing. If this is the case, then Ruga must renegotiate the agreement before any grant funds are disbursed to the company to ensure that potential investors are not disincentivized. CPRIT's Chief Product Development Officer, with the input of the PDRC if necessary, should review the FDBT agreement and advise the CPRIT CEO regarding whether to execute the contract.

Within six months of executing the award contract, Ruga must hire:

- A Chief Medical Officer with a regulatory background and a demonstrated history of product(s) approval;
- A Program Manager to manage the development program and the consultants; and
- A full-time outward-facing CEO who is responsible for strategy and engaging with strategic partners, including potential investors and regulatory professionals.

The PDRC's strong recommendation of the proposed project is tempered by its concern regarding the ability of Ruga's current management to professionally manage the project. While the "virtual structure" approach outlined by the company is generally acceptable, the company's reliance upon contracted research personnel and the ability of the current CEO to devote time and expertise to steering the project through the FDA approval process raise questions that should be quickly addressed by the company. The company needs full-time executive leadership as well as some key hires with regulatory approval expertise to interface with the contracted research personnel.

The PDRC will approve achievement of this objective as part of CPRIT's tranche report approval process. Ruga may consult with the Chief Product Development Officer prior to making final offers.

Within Year 1 of the project timeline, Ruga must:

 Achieve production of their construct and formulation of the final recombinant decoy receptor Ruga plans to develop with FDBT.

The PDRC notes that the company's proposed timeline for the IND timeline may be optimistic. Therefore, the PDRC recommends that as part of the Project Year 1 tranche Ruga achieves production of their construct and formulation of the final recombinant decoy receptor they are planning to develop with FDBT. This will prepare the company for its discussions with the FDA and planned IND submission, so as to receive the FDA's concurrence of Ruga's plan.

The PDRC will approve achievement of this objective as part of CPRIT's tranche report approval process.

Sincerely, /JG/

Jack Geltosky Chairman, Product Review Council



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

November 16, 2015

Oversight Committee Members,

Pursuant to 25 T.A.C. § 703.7(j), I request that the Oversight Committee approve authority for CPRIT to advance grant funds upon execution of a grant contract for one company that will be considered for Product Development grant awards at the November 19, 2015, Oversight Committee meeting. The company has been recommended for a grant award by the Program Integration Committee (PIC). The Oversight Committee will consider the PIC's recommendation at the November 19, 2015, Oversight Committee meeting.

Although CPRIT disburses the majority of grant funds pursuant to requests for reimbursement, CPRIT may disburse grant funds in advance payments consistent with the General Appropriations Act, Article IX, § 4.03(a). Typically, the grant amount to be paid in advance is based upon the project year budget or tranche amount. All grant recipients, including those that receive advance payment of grant funds, are required to submit quarterly financial status reports that are reviewed and approved by CPRIT's financial staff. Failure to submit the financial status reports on a timely basis will result in forfeiture of reimbursement for expenses for the quarter and may result in grant termination and repayment of grant funds.

After consultation with Mr. Michael Lang, CPRIT's Chief Product Development Officer, the following reason supports advance payment of grant funds for the company: pre-clinical trial contracts will need to be entered into with substantial upfront payments.

Sincerely,

Wayne R. Roberts,

CPRIT Chief Executive Officer



CEO Affidavit Supporting Information

FY 2015—Cycle 4
New Company Product Development Awards

Request for Applications



REQUEST FOR APPLICATIONS RFA C-15-NEWCO-2

New Company Product Development Awards

Please also refer to the Instructions for Applicants document, which will be posted January 5, 2015

Application Receipt Opening Date: January 5, 2015

Application Receipt Closing Date: February 9, 2015

FY 2015

Fiscal Year Award Period

September 1, 2014-August 31, 2015

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RFA VERSION HISTORY

Rev 12/01/14	RFA release
Rev 12/02/14	Added section 2.1: Product Development Program Priorities
	Added the last paragraph to section 6
Rev 1/07/15	Changed page limit of section 11.4.8 (Scientific Plan) from 10 to 15 pages
	Moved the Competitive Landscape/Intellectual Property Plan from the Business
	Plan to a separate section (11.4.10; page 25)

1. KEY POINTS

This New Company Product Development Award mechanism is governed by the following restrictions:

- Company applicants must be early-stage startup companies with no previous round of
 professional institutional investment (ie, those that have not yet received Series A
 financing or a substantive equivalent). Companies at this early stage that are not currently
 located in Texas but intend to relocate to Texas should apply under this mechanism rather
 than the Company Relocation Awards mechanism.
- Recipient companies must currently have or must commit to the following: Headquarters
 or substantial business functions of the company in Texas; personnel sufficient to operate
 the Texas-based research and/or development activities of the company, along with
 appropriate management, relocated to or hired from within Texas.
- Of the total program budget, the Cancer Prevention and Research Institute of Texas (CPRIT) will contribute \$2.00 for every \$1.00 contributed, in matching funds, by the company. The demonstration of available matching funds must be made prior to the distribution of CPRIT grant funds, not at the time the application is submitted. CPRIT funds must, whenever possible, be spent in Texas. A company's matching funds must be targeted for the CPRIT-funded project but may be spent outside of Texas.
- CPRIT's contribution to the program will not be greater than \$20 million.
- Funding will be tranched and will be tied to the achievement of contract-specified milestones.
- Funding award contracts will include a revenue-sharing agreement according to CPRIT's
 policies in force at the time of the award and will require CPRIT to have input on any
 future patents, agreements, or other financial arrangements related to the products,
 services, or infrastructure supported by the CPRIT investment. These contract provisions
 are specified in CPRIT's Administrative Rules, which are available at
 www.cprit.state.tx.us.

2. ABOUT CPRIT

The state of Texas has established CPRIT, which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the state of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the
 development and coordination of effective and efficient statewide public and private
 policies, programs, and services related to cancer and by encouraging cooperative,
 comprehensive, and complementary planning among the public, private, and volunteer
 sectors involved in cancer prevention, detection, treatment, and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

2.1. Product Development Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The Product Development Program's principles and priorities will also guide CPRIT staff and the Product Development Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

Established Principles:

- Moving forward the development of commercial products to diagnose and treat cancer and improve the lives of cancer patients
- Creation of good, high-paying jobs for Texans
- Sound financial return on the monies invested
- Development of the Texas high tech life sciences business environment

Product Development Program Priorities

- Funding projects at Texas companies and relocating companies that are most likely to bring important products to the market
- Providing funding that promotes the translation of research at Texas institutions into new companies able to compete in the marketplace
- Identifying and funding projects to develop tools and technologies of special relevance to cancer research, treatment, and prevention

3. APPLICANT SURVEY

CPRIT will be administering a survey to determine the operational aspects of peer review. Company representatives that anticipate submitting an application are requested to complete the survey as soon as possible, but no later than January 19, 2015. Company representatives should provide the following information: Applicant name, name of company, telephone number, e-mail address, estimated award amount, and award mechanism. Please select only 1 award mechanism as only 1 application can be submitted per funding cycle. This information will be used for planning purposes only and will not be used for evaluation of the application. The survey is available here.

4. EXECUTIVE SUMMARY

CPRIT will foster the creation of high-quality new jobs in Texas by providing financial support for a wide variety of projects relevant to cancer. This Request for Applications (RFA) is designed to support the formation of oncology-focused companies in Texas. CPRIT expects outcomes of supported activities to directly and indirectly benefit subsequent cancer research

efforts, cancer public health policy, or the continuum of cancer care—from prevention to treatment and cure. To fulfill this vision, applications may address any product development topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, or cure. The overall goal of this award program is to improve outcomes of patients with cancer by increasing the availability of Food and Drug Administration (FDA)—approved therapeutic interventions with a primary focus on Texas-centric programs.

5. MECHANISM OF SUPPORT

The goal of the New Company Product Development Awards is to finance the research and development of innovative products, services, and infrastructure with significant potential impact on patient care. These investments will assist early-stage startup companies by providing the opportunity to further the research and development of new products for the diagnosis, treatment, supportive care, or prevention of cancer; to establish infrastructure that is critical to the development of a robust industry; or to fill a treatment, industry, or research gap. This award mechanism will support companies that intend to undertake product research and development in Texas with a strong presence of Texas-based employees. In determining eligibility for this award, CPRIT will evaluate whether applicants have a significant presence in Texas or are willing to relocate to Texas.

6. OBJECTIVES

The state of Texas seeks to attract industry partners in the field of cancer care to advance economic development and cancer care efforts in the state. The goal of this award mechanism is to support the formation and establishment of new startup companies in Texas that will develop products to significantly impact cancer care. These companies must be Texas based or have personnel sufficient to operate the Texas-based research and/or development activities of the company, along with appropriate management, who are willing to relocate to or be hired and remain in Texas for a specified period after funding. Eligible products or services include—but are not limited to—therapeutics (eg, small molecules and biologics), diagnostics, devices, and potential breakthrough technologies, including software and research discovery techniques. Eligible stages of research and development include translational research, proof-of-concept studies, preclinical studies, and Phase I or Phase II clinical trials. By exception, Phase III clinical

trials and later stage product development projects will be considered where circumstances warrant CPRIT investment.

CPRIT's objectives and program priorities are established by its Oversight Committee. Consistent with the above, these priorities include, "funding projects at Texas companies and relocating companies that are most likely to bring important products to the market." A full description of CPRIT's program priorities may be found at http://www.cprit.state.tx.us/about-cprit/reports/.

7. FUNDING INFORMATION

This is a 3-year funding program. Financial support will be awarded based upon the breadth and nature of the research and development program proposed. While requested funds must be well justified, there is no limit on the amount that may be requested. Funding will be milestone driven.

Funds may be used for salary and fringe benefits, research supplies, equipment, clinical trial expenses, intellectual property protection, external consultants and service providers, and other appropriate research and development costs, subject to certain limitations set forth by Texas state law. If a company is working on multiple projects, care should be taken to ensure that CPRIT funds are used to support activities directly related to the specific project being funded. Requests for funds to support construction and/or renovation may be considered under compelling circumstances for projects that require facilities that do not already exist in the state of Texas. Texas state law limits the amount of awarded funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs).

Consistent with statutory mandate, of the total program budget, CPRIT will contribute \$2.00 for every \$1.00 contributed, in matching funds, by the company. The demonstration of available matching funds must be made prior to the distribution of CPRIT funds, not at the time the application is submitted. The matching funds commitment may be made on a year-by-year basis.

8. KEY DATES

RFA release December 1, 2014

Online application opens January 5, 2015, 7 AM central time

Applications due February 9, 2015, 3 PM central time

Invitations to present sent April 2015

Notifications sent if not invited April 2015

Presentations to CPRIT* April 2015

Award Notification August 2015

Anticipated Start Date September 2015

9. ELIGIBILITY

9.1. New Applications

- Early-stage startup companies are eligible. Such companies may have received seed funding from family, friends, and/or angel investors. However, only applicants with no previous round of professional institutional investment (ie, those that have not yet received Series A financing or a substantive equivalent) are eligible. The inclusion of a complete and detailed capitalization table is required for assessment of eligibility.
- Recipient companies must commit to the following: Headquarters or substantial functions of the company in Texas; personnel sufficient to operate the Texas-based research and/or development activities of the company, along with appropriate management, relocated to or hired from within Texas who will remain in Texas for a specified period after funding; and use of Texas-based subcontractors and suppliers unless adequate justification is provided for the use of out-of-state entities. To the extent that Texas-based subcontractors or collaborators are not available, non–Texas-based collaborators and subcontractors may

^{*}Applicants will be notified of their peer review panel assignments prior to the peer review meeting dates. Information on the timing of subsequent steps will be provided to applicants later in the process.

- be used. However, non-Texas-based collaborators and subcontractors are not eligible to receive funds from CPRIT unless exceptional circumstances are demonstrated and approved by CPRIT.
- In general, a greater extent of commitment to establishing research and/or development functions in Texas will be viewed more favorably by CPRIT. However, it is left to the applicant's judgment to make a case for what they consider to be a sufficient extent of commitment to Texas.
- An applicant may submit only 1 application under this RFA during this funding cycle.
- A company applicant is eligible to receive a grant award only if the applicant certifies that the company, including the company representative, any senior member or key personnel listed on the application, or any company officer or director (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity) has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- A company applicant is not eligible to receive CPRIT funding if the company representative, any senior member or key personnel listed on the application, or any company officer or director is related to a CPRIT Oversight Committee member.
- The company applicant must report whether the company, company representative, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful company applicants. Certain contractual requirements are mandated by Texas state law or by administrative rules. Although the company applicant need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should familiarize themselves with these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 12 and section 13. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

9.2. Resubmission Policy

An application previously submitted to CPRIT but not funded may be resubmitted once and must follow all resubmission guidelines (see section 11.4.5). An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the applicant or company representative for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission. Applicants who choose to resubmit should carefully consider the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes. A 1-page summary of the approach to the resubmission should be included. Resubmitted applications may be assigned to reviewers who did not review the original submission. Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. Applicants should note that addressing previous critiques is advisable; however, it does not guarantee the success of the resubmission. All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

9.3. Renewal Policy

Grant recipients that have previously received CPRIT grant funding may submit an application for competitive renewal under the Established Company Product Development Award RFA. Before submitting a renewal application, applicants must consult with the Product Development Programmatic Office (see section 14.2) to determine whether it is appropriate for their company to seek renewal funding at this time.

10. APPLICATION REVIEW

10.1. Overview

Applications will be assessed based on evaluation of the quality of the company and the potential for continued product development. CPRIT requires the submission of a comprehensive scientific plan (see section 11.4.8) and a detailed business plan (see section 11.4.9). The review will address the commercial viability, product feasibility, scientific merit, and therapeutic impact as detailed in the company's business and scientific plans. The plans will be reviewed by an integrated panel of individuals with biotechnology expertise and experience in translational and clinical research as well as in the business development/regulatory approval processes for therapeutics, devices, and diagnostics. In addition, advocate reviewers will participate in the review process.

Funding decisions are made by the review process described below.

10.2. Review Process

- 1. Product Development and Scientific Review: Applications that pass initial administrative compliance review are assigned to independent CPRIT Product Development Peer Review Panel members for evaluation using the criteria listed below. Based on the initial evaluation and discussion by the Product Development Review Panel, a subset of company applicants may be invited to deliver in-person presentations to the review panel.
- 2. Due Diligence Review: Following the in-person presentations, a subset of applications judged to be most meritorious by the Product Development Review Panels will be referred for additional in-depth due diligence, including—but not limited to—intellectual property, management, regulatory, manufacturing, and market assessments. Following the due diligence review, applications will be recommended for funding by the CPRIT Product Development Review Council based on the information set forth in the due diligence and intellectual property reviews, comparisons with applications from the Product Development Review Panels, and programmatic priorities.

- 3. Program Integration Committee Review: Applications recommended by the Product Development Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding.
- **4. Oversight Committee Approval:** The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote.

The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6–703.8.

10.2.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Product Development Peer Review Panel members, Product Development Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Product Development Peer Review Panel members and Product Development Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.

Communication regarding the substance of a pending application is prohibited between the company applicant (or someone on the applicant's behalf) and the following individuals: An Oversight Committee member, a PIC member, a Product Development Review Panel member, or a Product Development Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

10.3. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. The overall assessment will not be an average of the scores of the individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.

10.3.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study.

Primary criteria include the following:

Significance and Impact: Will the outcomes of this CPRIT-funded work result in the development of innovative products with significant product development potential? Will the outcome substantially impact the diagnosis, treatment, prevention of cancer, or supportive care for patients with cancer? How would competing products or services affect the value of the proposed offering?

Product: Is there demonstrated proof of relevance, and does the product fulfill a clear, unmet medical or infrastructure need? Has work been conducted that supports the advancement of the proposed product, service, or technology? Can the product be produced or manufactured in a commercially viable fashion? Is there an appropriate basis for a reimbursement strategy?

Market Plan: Is there a realistic assessment of the market size and expected penetration? Has management adequately assessed potential competitors and described how the company's offering will successfully compete with them?

Development Plan and/or Regulatory Path: Is the development plan and/or regulatory path well characterized and appropriate? Is the plan milestone driven, and does it address both a positive and a negative outcome? Does the budget appropriately support the plan?

Competitive Landscape/Intellectual Property: Are you aware of the competitive landscape related to your project? Has the regulatory pathway been adequately described? Have intellectual property issues been addressed?

Scientific Plan: Is the proposed product, service, and/or infrastructure based on a feasible research framework, hypothesis, and/or goal? Are the methods appropriate, and are potential research and developmental obstacles and unexpected outcomes discussed?

Management and Staffing: Does the applicant have the appropriate level of management experience to execute the stated strategy in Texas, especially if the headquarters of the company are not in Texas? Would the proposed team have the needed experience or access to experienced external assistance, facilities, and resources to accomplish all aspects of the proposed plan?

10.3.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed research and development activities.

Secondary criteria include the following:

Budget and Duration of Support: Are the budget and duration appropriate for the proposed work? Will the amount requested enable the applicant to reach appropriate milestones? Is the use of the funds requested in line with the stated objectives of the applicant and CPRIT? Is it clear

how funds will be used (Does the use of funds indicate a commitment to conducting the project work in Texas? Is it clear that no CPRIT funds will be sent to the corporate headquarters if those headquarters remain outside of Texas)? Does the proposed investment fund the research and development of the proposed product, service, or technology to a point where, if the results are positive, it is likely that the project will be able to attract further financial support outside of CPRIT?

11. SUBMISSION GUIDELINES

Applicants are advised to carefully review all instructions in this section to ensure the accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Applications that are missing 1 or more components, exceed the specified page or word limits, or that do not meet the eligibility requirements listed above will be administratively withdrawn without review.

11.1. Online Application Receipt System and Application Submission Deadline

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The company applicant must create a user account in the system to start and submit an application. The coapplicant, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (ASO) (an individual authorized to sign and submit an application on behalf of the company applicant) must also create a user account in CARS. An application may not be submitted without ASO approval. Only the ASO is authorized to officially submit the application to CPRIT. Applications will be accepted beginning at 7 AM central time on January 5, 2015, and must be submitted by 3 PM central time on Feburary 9, 2015. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

11.2. Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via e-mail to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

11.3. Product Development Review Fee

All applicants must submit a fee of \$1,000 for product development review. Payment should be made by check or money order payable to CPRIT; electronic and credit card payments are not acceptable. The application ID and the name of the submitter must be indicated on the payment. Unless a request to submit a late fee has been approved by CPRIT, all payments must be postmarked by the application submission deadline and mailed to the following address:

Cancer Prevention and Research Institute of Texas P.O. Box 12097 Austin, TX 78711

11.4. Application Components

Applicants are advised to minimize repetition between application components to the extent possible. In addition, Applicants should use discretion in cross-referencing sections in order to maximize the amount of information presented within the page limits.

11.4.1. Abstract and Significance (5,000 characters)

Clearly explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the research plan. Clearly address how the proposed project, if successful, will have a major impact on care of patients with cancer. Explain how this application provides a clear path for acquiring proof-of-principle data necessary for next-stage commercial development.

11.4.2. Layperson's Summary (1,500 characters)

Provide an abbreviated summary for a lay audience using clear, nontechnical terms. Describe specifically how the proposed project would support CPRIT's mission (see section 2). Would it fill a needed gap in patient care or in the development of a sustainable oncology industry in Texas? Would it synergize with Texas-based resources? Describe the overall goals of the work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the fields of diagnosis, treatment, or prevention of cancer. Clearly address how the company's work, if successful, will have a major impact on the care of patients with cancer. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. The Layperson's Summary will also be used by advocate reviewers in evaluating the significance and impact of the proposed work. Do not include any proprietary information in this section.

11.4.3. Goals and Objectives (1,200 characters each)

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success.

11.4.4. Timeline (1 page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

11.4.5. Resubmission Summary (1 page)

If this is a resubmission, upload a summary of the approach, including a summary of the applicant's response to previous feedback. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When

a resubmission is evaluated, responsiveness to previous critiques is assessed. If this is not a resubmission, then no summary is required.

Note: An application is a resubmission only if the previous application was finalized and submitted to CPRIT. However, an application that was submitted to CPRIT to be considered for FY2013 Cycle 3 awards and was returned by CPRIT due to the moratorium is not considered to be a resubmission.

11.4.6. Executive Summary (1 page)

Provide an executive summary that clearly explains the product, service, technology, or infrastructure proposed; competition; market need and size; development or implementation plans; regulatory path; reimbursement strategy; and funding needs. Applicants must clearly describe the existing or proposed company infrastructure and personnel located in Texas for this endeavor.

11.4.7. Slide Presentation (10 pages)

Provide a slide presentation summarizing the application. The presentation should be submitted in PDF format, with one slide filling each landscape-orientation page. The slides should succinctly capture all essential elements of the application and should stand alone.

11.4.8. Scientific Plan (15 pages)

Present the rationale behind the proposed product or service, emphasizing the pressing problem in cancer care that will be addressed. Summarize the evidence gathered to date in support of the company's ideas. Describe the label claims that the company ultimately hopes to make, and describe the plan to gather evidence to support these claims. Outline the steps to be taken during the proposed period of the award, including the design of the translational or clinical research, methods, and anticipated results. Describe potential problems or pitfalls and alternative approaches. If clinical research is proposed, present a realistic plan to accrue a sufficient number of human subjects meeting the inclusion criteria within the proposed time period.

The Scientific Plan should include a defined Target Product Profile, that projects a clear path to full commercial development. The Target Product Profile should include the parameters below; the questions are intended to guide the thinking process and may include, but are not limited to, the examples provided.

- 1. Identification of a target that is applicable to human cancer treatment. Is intervention with this target likely to lead to a therapeutic, diagnostic, or medical device that could be useful in the treatment of cancer?
- **2. Selection of a lead compound, assay, or device technology based on the target.** Is the identification of potential developmental candidates based on a set of in vitro tests followed by selection of a lead candidate based on considerations (as appropriate for the candidate) of pharmacodynamic parameters and the results of preclinical, in vivo, proof-of-principle studies in relevant animal models of disease?
- **3. Description of a high-level clinical development plan detailing each of the clinical studies the preclinical work is meant to support.** Designing the preclinical program requires an understanding of the duration of the clinical studies required by regulatory authorities. Consequently, a brief outline of each of the Phase I, Phase II, and Phase III studies necessary to obtain regulatory approval and reimbursement funding must be sketched out prior to deciding which toxicology studies would be required.

Additionally, for therapeutics the following apply:

Intended route of administration and dosing regimen. Is the intended route of administration and dosing regimen consistent with accepted convention and medical need for the therapeutic, or will the use of this new agent require a paradigm shift (more frequent or less frequent dosing, new route of administration), and if so, what impact will it have on current standard of care?

Optimization of the lead to ensure desired characteristics, including, but not limited to, the following studies:

- **1. Absorption, distribution, metabolism, excretion (ADME),** including, but not limited to, relevant studies based on route of administration.
- 2. Safety (studies as mandated by ICH Guidelines).

- 3. Biomarkers (assays) that potentially target specific patient populations for clinical trials.
- **4. Biomarkers (assays) that can serve as potential pharmacodynamic markers** of clinical activity during early clinical trials designed to demonstrate proof-of-concept.
- **5. Proposed current Good Manufacturing Practice (cGMP)** (including estimated costs) that can be scalable from Phase I through Phase III. Include information if there are possible plans for formulation.

The scientific plan submitted must be of sufficient depth and quality to pass rigorous scrutiny by the highly qualified group of reviewers. To the extent possible, the scientific plan should be driven by data. In the past, applications that have been scored poorly have been criticized for assuming that assertions could be taken on faith. Convincing data are much preferred.

11.4.9. Business Plan (15 pages)

Provide a business plan covering all of the topics below in the order shown. Successful applicants will make thoughtful, careful, and economical use of the limited space. Note that if the company is selected to undergo due diligence, information to support a full intellectual property review will be requested at that time. New Company Product Development Award applicants will be evaluated based not only on the current status of the components of the business plan but also on whether current weaknesses and gaps are acknowledged and whether plans to address them are outlined.

- **A. Products and Markets:** Provide a brief description of the envisioned product and how the product will be administered to patients. Describe the initial market that will be targeted and how the envisioned product will fit within the standard of care.
- **B. Regulatory Plans:** Provide a detailed regulatory plan, including preclinical and clinical activities, driven by interactions with the FDA, if possible. Summarize all interactions to date with the FDA

- **C. Risk Analysis:** Describe the specific risks inherent to the product plan and how they would be mitigated.
- **D.** Current and Pending Support: Describe all funding sources. Provide a complete and detailed capitalization table, which should include all parties who have investments, stock, or rights in the company. The identities of all parties must be listed. It is not appropriate to list any funding source as anonymous.
- **E. Financial Projections:** Provide a detailed source and use analysis of the development plan, focusing on the achievement of specific milestones.
- **F. Resources Requested:** Include resources needed for research and product development and for any relocation expenses. The matching funds should be included in this section; however, this is the only section of the business plan that does not deal exclusively with CPRIT-requested funds.
- G. Scope of Work and Milestones: Outline the specific goals of the project. Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract.
- H. Key Personnel Located in Texas and Any Key Management Located Outside of Texas: Present a plan for recruiting a senior management and scientific team, describing the types of expertise and skillsets that the project will require. For each key person currently on board, provide a paragraph briefly summarizing his or her present title and position, prior industry experience, education, and any other information considered essential for evaluation of qualifications.
- I. Organizational Commitment to Texas: Describe how CPRIT funding of the applicant's company would benefit the state of Texas. For example, describe how the company would create high-quality new jobs in the state and/or recruit out-of-state talent, and mention any Texas-based subcontractors and suppliers that would be used and any other unique, Texas-based resources that would be leveraged.

11.4.10. Competitive Landscape/Intellectual Property (5 pages)

Complete the Competitive Landscape/Intellectual Property Plan using the template provided on the CARS (https://CPRITGrants.org). Provide a clear discussion of the competitive landscape related to your project, including any companies/university laboratories working on similar projects; indicate which of these projects constitute the greatest competitive threat. Describe how your project compares with your competitors, and indicate any potential opportunities for partnering with them. Provide a concise discussion of the intellectual property issues related to your project and list any relevant issued patents and patent applications, along with their titles and dates they were filed/published/issued. In addition, list any licensing agreements that your company has signed that are relevant to this application.

11.4.11. Relocation Commitment to Texas (1 page)

If your company will be relocating to Texas, provide a timetable with key dates indicating the applicant's plan and commitment to relocate to Texas. In addition, describe which personnel and management will be headquartered in Texas.

11.4.12. Biographical Sketches of Key Scientific Personnel (8 pages)

Provide a biographical sketch for up to 4 key scientific personnel that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed two pages and must use the "Product Development Programs: Biographical Sketch" template. (In addition, information on the members of the senior management and scientific team should be included in the "Key Personnel" section of the Business Plan [see section 11.4.9]).

11.4.13. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. The budget must be aligned with the proposed milestones. In preparing the requested budget, applicants should be aware of the following:

- Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas state law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us.
- The annual salary that an individual may receive under a CPRIT award for FY 2015 is \$200,000. In other words, an individual may request salary proportional to the percentage effort up to a maximum of \$200,000. Salary does not include fringe benefits. CPRIT FY 2015 is from September 1, 2014, through August 31, 2015.

12. AWARD ADMINISTRATION

Texas law requires that CPRIT awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to entities, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. Applicants are advised to review CPRIT's Administrative Rules related to

contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10 to 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

Project Economics Sharing: Recipients should also be aware that the funding award contract will include a revenue-sharing agreement and will require CPRIT to have input on any future patents, agreements, or other financial arrangements related to the products, services, or infrastructure supported by the CPRIT investment. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us.

13. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas state law requires that prior to disbursement of CPRIT grant funds, the award recipient demonstrate that it has \$1.00 in matching funds for every \$2.00 from CPRIT. Matching funds need not be in hand when the application is submitted. However, matching funds must be obtained before CPRIT funds will be released for use. CPRIT funds must, whenever possible, be spent in Texas. A company's matching funds must be designated for the CPRIT-funded project but may be spent outside of Texas. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements associated with demonstration of available funds.

14. CONTACT INFORMATION

14.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via e-mail will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding scientific and commercialization aspects of applications. Before contacting the HelpDesk, please refer to the *Instructions for Applicants* document, which provides a step-by-step guide on using CARS.

Dates of operation: January 5, 2015, to February 9, 2015 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time

Wednesday, 8 AM to 4 PM central time

Tel: 866-941-7146

E-mail: <u>Help@CPRITGrants.org</u>

14.2. Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Product Development Program Director.

Tel: 512-305-8419

E-mail: <u>Help@CPRITGrants.org</u>

Website: www.cprit.state.tx.us

Third Party Observer Report

CPRIT Product Development Peer Review Panel Observation Report

Report #2015-224

Panel Name: FY15.4 Product Development Panel-1

Panel Date: March 26, 2015 Report Date: March 30, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the peer review of Product Development to determine which grants would be invited to make in-person presentations. The meeting was chaired by Jack Geltosky and held via teleconference on March 26, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The panelists' discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the peer review panel meeting held at via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Jack Geltosky on March 26, 2015.

The independent observer noted the following during our observation:

- Twelve applications were discussed within the Product Development Peer Review Panel to determine which grants would be invited to make in-person presentations in Dallas.
- Thirteen reviewers, three advocate reviewers, three CPRIT staff members and three SRA employees were
 present for the meeting.
 - One of the thirteen reviewers participated as an ad hoc reviewer for one application.

- Five conflicts of interest were identified prior to or during the meeting. The reviewers with the conflicts of interest dropped off the call and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the panel's discussion of scientific, technical or programmatic aspects of the applications.

The independent observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Product Development Peer Review Panel Report

Report #2015-228

Panel Name: FY15.4 Product Development Panel - 1

Panel Date: April 27, 2015 – April 28, 2015

Report Date: April 28, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Product Development Panel peer review for FY 15 funding. The meeting was chaired by Jack Geltosky and held in person on April 27, 2015 – April 28, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the
 meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The panelists' discussion is focused on the established scoring criteria.

Observation Results Summary

The independent observer participated in the Product Development peer review meeting. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Jack Geltosky on April 27, 2015 – April 28, 2015.

The independent observer noted the following during observation:

- Ten product development applications were discussed and evaluated by the Product Development Review
 Panel to determine which grants would be brought forth for further due diligence and funding.
- Twelve review panel members, one ad-hoc reviewer, two advocate reviewers, three SRA employees, and four CPRIT staff members were present for the in–person panel meeting.
- Twenty-five conflicts of interest were identified prior to or during the in-person review.

- Eighteen out of the twenty-five conflicts were related to the ten applications that were discussed during the panel.
- Ten out of the eighteen instances were for an individual who was not present at the peer review meeting.
- O The remaining six panel members with conflicts of interests left the room and did not participate in the review of the conflicted applications.
 - Two panel members identified that they had a conflicts of interest during the in-person presentation and notified the SRA and CPRIT members.
 - Once the SRA and CPRIT staff confirmed the conflicts of interest, the panel members left the room.
 - The panel members did not participate in the review process.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

 An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

The independent observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Product Development Review Council Meeting Observation Report

Report #2015-10-12-PDEV

Program Name: Product Development

Panel Name: FY15.4 Due Diligence Evaluation

Meeting 1

Panel Date: October 12, 2015 Report Date: October 20, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Due Diligence Evaluation Meeting 1 peer review of applications for FY15 funding. The meeting was chaired by Jack Geltosky and held via teleconference on October 12, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Due Diligence Evaluation meeting via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Jack Geltosky on October 12, 2015.

The independent observer noted the following during our observation:

- Three applications were discussed within the Due Diligence Evaluation Meeting to determine which
 grants would receive CPRIT funding.
- Seven peer review panelists, five CPRIT staff members, one SRA employee and one IP attorney was present via teleconference on October 12, 2015.
 - The IP attorney was present for two of the three applications discussed.
- One conflict of interest was identified prior to or during the meeting. Applications for one conflict was
 discussed during the peer review panel. The reviewer with the conflicts of interest either left the room
 or did not participate telephonically and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical
or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Product Development Cycle 15.4Applications (Product Development Cycle 15.4 Awards Announced at November 19, 2015, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Product Development Cycle 15.4 New Company Product Development Awards, Company Relocation Product Development Awards, and Established Company Product Development Awards. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted				
Applications considered by the PIC and Oversight Committee							
DP150127	Giaccia, Amato	Ruga Corporation	Pegram, Mark;				
			Sarisky, Robert;				
			Saxberg, Bo;				
Applications Not	Applications Not Recommended for PIC or Oversight Committee Consideration						
DP150125	Adams, Christopher	Andarix	Dhingra, Kapil;				
	P.	Pharmaceuticals, Inc.	Saxberg, Bo				
DP150118	Xu, Jeff	Digital Biopsy, Inc.	Dhingra, Kapil;				
			Saxberg, Bo;				
DP150119	Prasad, Sridhar	CalaAsia	Geltosky, Jack;				
		Pharmaceuticals, Inc.	Saxberg, Bo				
DP150120	Gunaratne, Preethi	University of	Saxberg, Bo				
		Houston					
DP150126	Holland, George	Aviara	Saxberg, Bo				
		Pharmaceuticals, Inc.					
DP150128	Carney, Darrell	Chrysalis	Saxberg, Bo				
		BioTherapeutics,					
		Inco.					
DP150129	Dada, Aspha	Biopep Solutions,	Saxberg, Bo				
		Inc.					
DP150130	Vankayalapati,	Oncolexis	Geltosky, Jack;				
	Hariprasad	Therapeutics, Inc.	Saxberg, Bo				
DP150132	Chiesi, Antonio	EXOSOMICS	Dhingra, Kapil;				
		SIENA SPA	Saxberg, Bo				
DP150133	Perrine, Michael	Agilvax, Inc.	Saxberg, Bo				
DP150134	Prendergast, John	Antyra, Inc.	Geltosky, Jack;				
			Saxberg, Bo				

Application ID	Applicant	Institution	Conflict Noted
DP150137	Bainbridge, Matthew	Codified Genomics,	Pegram, Mark;
		LLC	Saxberg, Bo
DP150138	Foster, David	Tuevol Therapeutics,	Saxberg, Bo
		Inc.	

High Level Summary of Due Diligence

High Level Summary of CPRIT Diligence and Recommendation

Ruga Corporation

The Product Development Review Council (PDRC), upon its review of the independent business and intellectual property due diligence performed on this application, has recommended to the Program Integration Committee that this application is suitable for CPRIT funding, with certain contract contingences noted in the recommendation letter.

One reviewer summarized the significance and impact of this proposal with the following words: "The approach used is innovative as it consists of using an engineered AXL Fx construct as a decoy receptor that acts as an antagonist to the receptor to its ligand Gas6. If successful, the outcome could substantially impact the treatment of AML as it would provide a new treatment approach."

The PDRC identified a potential problem with the licensing agreement with Standard University. Specifically, Ruga's current license agreement mandates a substantial return to Stanford (15% of all payments and milestones payments). Although CPRIT's investment in the project is significant, it is a small amount of the total capital necessary to bring the proposed therapy to patients. It is the PDRC's opinion that if the license terms remain in place, it will significantly affect Ruga's ability to raise necessary follow-on funding from investors. In addition, march-in rights included in the Stanford agreement place the company at risk of losing control of the project, another issue that will make prospective funders unwilling to participate in future fundraising rounds. Unless the Stanford agreement is renegotiated, CPRIT should not disburse any grant funds to the company.

The PRDC also identified a potential problem with the agreement with Fuji Diosynth Biotech of Texas (FDBT). Specifically, the PDRC is concerned that Ruga's agreement with FDBT may make the vector and expression system proprietary to the manufacturer with the reagents royalty-bearing. If this is the case, then Ruga must renegotiate the agreement before any grant funds are disbursed to the company to ensure that potential investors are not disincentivized.

If these issues are adequately addressed by the company, an award contract should be executed. The PDRC also noted certain key hires to be made in the first year of the project. The issues highlighted through due diligence can be managed and the PDRC concluded that overall this is an excellent project.

De-Identified Overall Evaluation Scores

New Company Product Development Awards

Product Development Research Cycle 15.4

Application ID	Final Overall Evaluation Score
DP150127*	2.2
а	3.3
b	4.3
С	4.7
d	5.0
е	6.1
f	6.3
g	6.5

^{*=}Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

Dear Pete and Wayne,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendation for CPRIT's product development research grant awards. The PDRC recommends that the Program Integration Committee and the Oversight Committee approve a \$20,000,000 product development research grant award to Ruga Corporation (Ruga), subject to certain contingencies and additional goals and objectives recommended by the PDRC as outlined below.

This recommendation reflects 50+ hours of individual review and panel discussion of the applicant's proposal as well as the PDRC's review of the due diligence reports. Our recommendation meets the PDRC's standards for grant award funding. These standards include the company's potential to: 1.) expedite innovation and product development in cancer research and treatments; 2.) create and expand the number of high-quality new jobs in Texas; and 3.) make a return on CPRIT's investment in cancer research.

The scientific rationale underlying Ruga's proposed product development research project is highly rated by the review panel, receiving an overall score of 2.2. The project as proposed may provide a more effective therapeutic option to acute myeloid leukemia and other aggressive cancers, including ovarian, endometrial, breast, renal and pancreatic.

The PDRC recommends the following contingencies, goals, and objectives be included in the grant award contract. The goals and objectives are in addition to those already specified by Ruga in its application.

Prior to contract execution but no later than May 1, 2016:

Ruga's licensing agreement with Stanford must be renegotiated. Unless CPRIT approves additional time, Ruga should provide the renegotiated license agreement to CPRIT by May 1, 2016.

Ruga's current license agreement mandates a substantial return to Stanford (15% of all payments and milestones payments). Although CPRIT's investment in the project is significant, it is a small amount of the total capital necessary to bring the proposed therapy to patients. It is the PDRC's opinion that if the onerous license terms remain in place, it will significantly affect Ruga's ability to raise necessary follow-on funding from investors. In addition, march-in rights included in the Stanford agreement place the company at risk of losing control of the project, another issue that will make prospective funders unwilling to participate in future fundraising rounds. Unless the Stanford agreement is renegotiated, CPRIT should not disburse any grant funds to the company.

CPRIT's Chief Product Development Officer, with the input of the PDRC if necessary, should review the renegotiated license and advise the CPRIT CEO regarding whether to execute the contract.

 Ruga should provide a copy of the agreement with Fuji Diosynth Biotech of Texas (FDBT) to CPRIT and follow recommendations, if any, regarding renegotiation. Should renegotiation of the FDBT agreement be necessary, it should be completed by May 1, 2016. Unless CPRIT approves additional time, Ruga should provide the renegotiated agreement to CPRIT by May 1, 2016.

The PDRC is concerned that Ruga's agreement with FDBT may make the vector and expression system proprietary to the manufacturer with the reagents royalty-bearing. If this is the case, then Ruga must renegotiate the agreement before any grant funds are disbursed to the company to ensure that potential investors are not disincentivized. CPRIT's Chief Product Development Officer, with the input of the PDRC if necessary, should review the FDBT agreement and advise the CPRIT CEO regarding whether to execute the contract.

Within six months of executing the award contract, Ruga must hire:

- A Chief Medical Officer with a regulatory background and a demonstrated history of product(s) approval;
- A Program Manager to manage the development program and the consultants; and
- A full-time outward-facing CEO who is responsible for strategy and engaging with strategic partners, including potential investors and regulatory professionals.

The PDRC's strong recommendation of the proposed project is tempered by its concern regarding the ability of Ruga's current management to professionally manage the project. While the "virtual structure" approach outlined by the company is generally acceptable, the company's reliance upon contracted research personnel and the ability of the current CEO to devote time and expertise to steering the project through the FDA approval process raise questions that should be quickly addressed by the company. The company needs full-time executive leadership as well as some key hires with regulatory approval expertise to interface with the contracted research personnel.

The PDRC will approve achievement of this objective as part of CPRIT's tranche report approval process. Ruga may consult with the Chief Product Development Officer prior to making final offers.

Within Year 1 of the project timeline, Ruga must:

 Achieve production of their construct and formulation of the final recombinant decoy receptor Ruga plans to develop with FDBT.

The PDRC notes that the company's proposed timeline for the IND timeline may be optimistic. Therefore, the PDRC recommends that as part of the Project Year 1 tranche Ruga achieves production of their construct and formulation of the final recombinant decoy receptor they are planning to develop with FDBT. This will prepare the company

for its discussions with the FDA and planned IND submission, so as to receive the FDA's concurrence of Ruga's plan.

The PDRC will approve achievement of this objective as part of CPRIT's tranche report approval process.

Sincerely, /JG/

Jack Geltosky Chairman, Product Review Council



CEO Affidavit Supporting Information

FY 2016—Cycle 1
Competitive Continuation/Expansion–Evidence-Based
Cancer Prevention Services

Request for Applications



REQUEST FOR APPLICATIONS RFA P-16-CCE-1

Competitive Continuation/Expansion for Evidence-Based Cancer Prevention Services

Please also refer to the "Instructions for Applicants" document, which will be posted April 30, 2015

Application Receipt Opening Date: April 30, 2015

Application Receipt Closing Date: July 9, 2015

FY 2016

Fiscal Year Award Period

September 1, 2015-August 31, 2016

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RFA VERSION HISTORY

Rev 4/16/15 RFA release

1. ABOUT CPRIT

The state of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the state of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Prevention Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The Prevention Program's principles and priorities will also guide CPRIT staff and the Prevention Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

Established Principles

- Fund evidence-based interventions and their dissemination
- Support the prevention continuum of primary, secondary, and tertiary (includes survivorship) prevention interventions

Prevention Program Priorities

- Prioritize populations and geographic areas of greatest need, greatest potential for impact
- Focus on underserved populations
- Increase targeting of preventive efforts to areas where significant disparities in cancer incidence or mortality in the state exist

2. FUNDING OPPORTUNITY DESCRIPTION

2.1. Summary

The ultimate goals of the CPRIT Prevention Program are to reduce overall cancer incidence and mortality and to improve the lives of individuals who have survived or are living with cancer. The ability to reduce cancer death rates depends in part on the application of currently available evidence-based technologies and strategies. CPRIT will foster the primary, secondary, and tertiary prevention of cancer in Texas by providing financial support for a wide variety of evidence-based risk reduction, early detection, and survivorship interventions.

This Competitive Continuation/Expansion for Evidence-Based Cancer Prevention Services (CCE-EBP) RFA solicits applications seeking to continue or expand projects previously or currently funded under the Evidence-Based Cancer Prevention Services mechanism. This award mechanism is open only to previously or currently funded CPRIT Prevention projects.

The proposed projects must continue to provide evidence-based interventions in primary, secondary, and/or tertiary cancer prevention and control. The proposed program should be designed to reach and serve as many people as possible. Partnerships with other organizations that can support and leverage resources are strongly encouraged. A coordinated submission of a collaborative partnership program in which all partners have a substantial role in the proposed project is preferred.

Applicants wanting to continue or expand previously or currently funded projects focused on public education should submit applications to the Cancer Prevention Promotion and Navigation to Clinical Services (PN) mechanism.

2.2. Project Objectives

CPRIT seeks to fund evidence-based prevention and survivorship services that will do the following:

 Address multiple components of the cancer prevention and control continuum (e.g., provision of screening and navigation services in conjunction with outreach and education of the priority population as well as health care provider education);

- Offer effective and efficient systems of delivery of prevention services based on the
 existing body of knowledge about, and evidence for, cancer prevention in ways that far
 exceed current performance in a given service area;
- Offer systems and/or policy changes that are sustainable over time;
- Provide tailored, culturally appropriate outreach and accurate information on early detection, prevention, and survivorship to the public and/or health care professionals that result in a health impact that can be measured; and/or
- Deliver evidence-based survivorship services aimed at reducing the morbidity associated with cancer diagnosis and treatment.

2.3. Award Description

CPRIT's Competitive Continuation/Expansion for Evidence-Based Cancer Prevention
Services grants are intended to fund continuation or expansion of currently or previously funded projects that have demonstrated exemplary success, as evidenced by progress reports and project evaluations, and desire to further enhance their impact on priority populations. Detailed descriptions of results, barriers, outcomes, and impact of the currently or previously funded project are required (see outline of Project Plan, Section 4.4.4).

The projects proposed under this mechanism should NOT be new projects but should closely follow the intent and core elements of the currently or previously funded project. Established infrastructure/processes and fully described prior project results are required. Improvements and expansion (e.g., new geographic area, additional services, new populations) are strongly encouraged but will require justification. Expansion of current projects into geographic areas not well served by the CPRIT portfolio (see maps at http://www.cprit.state.tx.us/prevention/cprit-portfolio-maps/), especially rural areas or subpopulations of urban areas that are not currently being served, will receive priority consideration. CPRIT expects measurable outcomes of supported activities, such as a significant increase over baseline (for the proposed service area). It is expected that baselines will have already been established and that continued improvement over baseline is demonstrated in the current application. However, in the case of a proposed expansion where no baseline data exist for the priority population, the applicant must present clear plans and describe method(s) of measurement used to collect the data necessary to establish

a baseline. Applicants must demonstrate how these outcomes will ultimately impact cancer incidence, mortality, morbidity, or quality of life.

CPRIT also expects that applications for continuation **will not** require startup time, that applicants can demonstrate that they have overcome barriers encountered, and that applicants have identified **lasting systems changes** that improve results, efficiency, and sustainability. Leveraging of resources and plans for dissemination are expected and should be well described.

CPRIT requires applicants to deliver evidence-based interventions in at least 1 of the following clinical services areas (see <u>Section 2.3.2</u> for areas of emphasis):

- Delivery of vaccines that reduce the risk of cancer
- Evidence-based assessment and counseling services for behaviors established as increasing cancer risk
- Screening and early detection services
- Survivorship services

CPRIT considers counseling services (e.g., tobacco cessation, survivorship, exercise, and nutrition) as clinical services when provided on an individual basis or in small groups.

Applicants are **required** to conceptualize comprehensive projects **or provide a continuum of services** that would increase desired outcomes. This mechanism **will fund** case management/patient navigation if it is paired with the actual delivery of a clinical service. Applicants offering screening services must ensure that there is access to treatment services for patients with cancers that are detected as a result of the program and describe plans to provide access to treatment services. CPRIT strongly encourages projects to include broad-based education on cancer risk reduction and health lifestyle as one component of the education curriculum. Applicants offering survivorship services should include an individual needs assessment in addition to the clinical service.

Under this RFA, CPRIT will not consider the following:

• Continuation or expansion of projects originally funded under the Health Behavior Change through Public and/or Professional Education mechanisms. These projects

should apply to the Cancer Prevention Promotion and Navigation to Clinical Services RFA.

- Projects focusing on case management/patient navigation services <u>through</u> the treatment phase of cancer
- Projects requesting CPRIT funding for State Quitline services. Applicants proposing the utilization of Quitline services should communicate with the Tobacco Prevention and Control program prior to submitting a CPRIT grant application to discuss the services currently offered by the Texas Department of State Health Services (DSHS).
- Resources for the treatment of cancer or viral treatment for hepatitis
- **Prevention/intervention research.** Applicants interested in prevention research should review CPRIT's research RFAs (available at http://www.cprit.state.tx.us.)

2.3.1. Priorities

Types of Cancer: Applications addressing any cancer type(s) for which there is strong evidence of effectiveness and that are responsive to this RFA will be considered for funding.

Priority Populations: The age of the priority population and frequency of screening plans for provision of clinical services described in the application must comply with established and current national guidelines (e.g., US Preventive Services Task Force [USPSTF], American Cancer Society).

Priority populations are subgroups that are disproportionately affected by cancer. CPRIT-funded efforts must address 1 or more of these priority populations:

- Underinsured and uninsured individuals
- Geographically or culturally isolated populations
- Medically unserved or underserved populations
- Populations with low health literacy skills
- Geographic regions of the state with higher prevalence of cancer risk factors (e.g., obesity, tobacco use, alcohol misuse, unhealthy eating, sedentary lifestyle)
- Racial, ethnic, and cultural minority populations

 Other populations with low screening rates, high incidence rates, and high mortality rates, focusing on individuals never before screened or who are significantly out of compliance with nationally recommended screening guidelines (more than 5 years for breast/cervical cancers).

Geographic and Population Balance Priority: For applications submitted in response to this announcement, at the programmatic level of review conducted by the Prevention Review Council (see Section 5.1), priority will be given to projects that target geographic regions of the state and population subgroups that are not adequately covered by the current CPRIT Prevention project portfolio (see http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control and http://www.cprit.state.tx.us/funded-grants).

2.3.2. Specific Areas of Emphasis

Applications addressing any type of education and outreach programs that include navigation to and delivery of clinical services and that are responsive to this RFA will be considered. However, CPRIT has identified the following areas of emphasis for this cycle of awards.

A. Primary Prevention

Priority will be given to projects that, through evidence-based efforts, address and can positively influence local policy or systems change that can lead to sustainable change in desired health behaviors.

CPRIT is interested in applications focused on the following:

Tobacco Prevention and Control

- Decreasing tobacco use in areas of the state that have higher smoking rates per capita than other areas of the state.
- Health Service Regions (HSRs) 2, 4, and 5 have significantly higher tobacco use among adults than in other regions of the state. For more information about maps of HSRs, please visit http://www.dshs.state.tx.us/regions/state.shtm.

HPV Vaccination

- Increasing access to, delivery of, and completion of the HPV vaccine regimen to males and females through evidence-based intervention efforts.
 - HPV vaccine completion rates are low (15% for males and 39% for females)
 across the state compared to the CDC goals of 75% completion rates.¹

Liver Cancer

- Decreasing disparities in incidence and mortality rates for hepatocellular cancer (HCC)
 by increasing the provision of vaccination and screening for hepatitis B virus and
 screening for hepatitis C virus (following USPSTF guidelines), diagnostic testing,
 navigation that ensures access to viral treatment, and education on risk factors and on
 reducing transmission of hepatitis.
 - HCC incidence is significantly higher in Texas Hispanics, blacks, and Asian/Pacific Islanders than in non-Hispanic whites.²
 - Significantly higher HCC rates in Texas Hispanics versus the United States are driven by very high rates among Hispanics in South Texas.²
 - o Males have significantly higher incidence and mortality rates than females.²
 - Age at diagnosis is shifting toward younger patients, both in Texas and the United States.²

B. Secondary Prevention - Screening and Early Detection Services

Applicants should select preventive services using current evidence-based national clinical guidelines (e.g., USPSTF, American Cancer Society).

Colorectal Cancer

- Increasing screening/detection rates in HSRs 1 through 6 and HSR 9.
 - The highest rates of cancer incidence mortality are found in these regions of Texas.²

- Decreasing disparities in incidence and mortality rates of colorectal cancer for racial/ethnic populations and rural communities.
 - African Americans have the highest incidence and mortality rates, followed by non-Hispanic whites and Hispanics.²
- Decreasing incidence and mortality rates in rural counties.
 - Incidence and mortality rates are higher in rural counties compared to urban counties.²

Cervical Cancer

- Increasing screening/detection rates for women in Texas-Mexico border counties.
 - Women in these counties have a 30% higher cervical cancer mortality rate than women in nonborder counties.²
- Decreasing disparities in racial/ethnic populations.
 - Hispanics have the highest incidence rates, while African Americans have the highest mortality rates.²
- Reaching women never before screened

Breast Cancer

- Increasing screening/detection rates in rural and medically underserved areas of the state
- Reaching women never before screened

Data on cancer incidence and mortality are provided by the Texas Cancer Registry.² For more information about cancer in Texas, visit CPRIT's website at

http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control or visit the Texas Cancer Registry site at http://www.dshs.state.tx.us/tcr/.

C. Tertiary Prevention - Survivorship Services

Priority for funding will be given to survivorship projects that demonstrate a likelihood of success based on available evidence and that can demonstrate and measure an improvement in quality of life in 1 of more of the following areas:

• Preventing secondary cancers and recurrence of cancer

- Managing the aftereffects of cancer and treatment to maximize quality of life and number of years of healthy life
- Minimizing preventable pain, disability, and psychosocial distress

Applicants proposing survivorship projects may address people with any type of cancer.

2.3.3. Outcome Metrics

The applicant is required to describe the results (quantitative and qualitative) of the currently or previously funded project and the proposed outcome measures/metrics for the current application. Interim measures that are associated with the final outcome measures should be identified and will serve as a measure of program effectiveness and public health impact. Applicants are required to clearly describe their assessment and evaluation methodology and to provide results and baseline data from currently or previously funded projects. Applicants should describe how funds from the proposed CPRIT grant will improve and expand outcomes from the initial project and how the current application builds on the previous work or addresses new areas of cancer prevention and control services. If the applicant is not providing baseline data for a measure, the applicant must provide a well-justified explanation and describe clear plans and method(s) of measurement to collect the data necessary to establish a baseline.

Reporting Requirements

Funded projects are required to report quantitative output and outcome metrics (as appropriate for each project) through the submission of quarterly progress reports, annual reports, and a final report.

- Quarterly progress report sections include, but are not limited to the following:
 - Narrative on project progress (required)
 - People reached activities
 - o Services, other than clinical services, provided to the public/professionals
 - Actions taken by people/professionals as a result of education or training, including percentage of people reporting sustained behavior change
 - Clinical services provided
 - Abnormal results and precursors or cancers detected

- Annual and Final progress report sections include, but are not limited to the following:
 - Key accomplishments, including qualitative analysis of policy change and/or lasting systems change
 - Progress against goals and objectives, including percentage increase over baseline in provision of age- and risk-appropriate comprehensive preventive services to eligible men and women in a defined service area, for example:
 - Percentage increase over baseline in number of people served
 - Percentage increase over baseline in number of services provided
 - Completion of all required doses of vaccine
 - Number of people quitting tobacco use and sustaining healthy behavior
 - Percentage increase over baseline in cancers detected
 - Percentage increase in early-stage cancer diagnoses in a defined service area
 - Materials produced and publications
 - Economic impact of the project

Outcome measures/metrics (as appropriate for each project) should be reported in the annual and final reports and should include, **but are not limited to**, the following:

For Primary Preventive Services

- Percentage increase over baseline in provision of age- and risk-appropriate
 comprehensive preventive services to eligible men and women in a defined service area
- Percentage of people reporting sustained behavior change
- Estimates of cancers prevented as a result of primary preventive services

For Screening Services

- Percentage increase over baseline in provision of age- and risk-appropriate
 comprehensive preventive services to eligible men and women in priority populations
- Percentage increase over baseline in early-stage cancer diagnoses in a defined service area

For Survivorship Services

- Percentage increase over baseline in provision of survivorship services in a defined service area
- Percentage increase over baseline in improvement in quality-of-life measures using a validated quality-of-life instrument, if such an instrument is applicable to the project
- Percentage of people reporting sustained behavior change
- Percentage of people showing clinical improvement of cancer treatment sequelae

Systems Change (for all projects)

- Qualitative analysis of policy or systems change
- Description of lasting, sustainable system changes

2.4. Eligibility

- The applicant must be a Texas-based entity that previously received CPRIT funding through Prevention Program RFAs.
- The designated Program Director (PD) will be responsible for the overall performance of the funded project. The PD must have relevant education and management experience and must reside in Texas during the project performance time.
- The evaluation of the project must be headed by a professional who has demonstrated expertise in the field (e.g., qualitative or quantitative statistics) and who resides in Texas during the time that the project is conducted.
- The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant may submit more than 1 continuation application, if eligible, but each application must be for distinctly different services without overlap in the services provided. Applicants who do not meet this criterion will have all applications

- administratively withdrawn without peer review. Applicants may submit a continuation application before the end of the currently funded project but should time their submission for continuation during the last year of the current project to ensure minimal overlap of funding. Unexpended funds from the original project will not carry forward to the continuation/expansion project. To apply for an expansion of a current project, projects must have at least 1 full year of results and data.
- If the applicant or a partner is an existing DSHS contractor, CPRIT funds may not be
 used as a match, and the application must explain how this grant complements or
 leverages existing state and federal funds. DSHS contractors who also receive CPRIT
 funds must be in compliance with and fulfill all contractual obligations within CPRIT.
 CPRIT and DSHS reserve the right to discuss the contractual standing of any contractor
 receiving funds from both entities.
- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Subcontracting and collaborating organizations may include public, notfor-profit, and for-profit entities. Such entities may be located outside of the state of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant organization is eligible to receive a grant award only if the applicant certifies that the applicant organization, including the PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization, (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation created to benefit CPRIT.
- The applicant must report whether the applicant organization, the PD, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way (whether slated to receive salary or compensation under the grant award or not), are currently ineligible to receive federal grant funds because of scientific misconduct or fraud or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

• CPRIT grants will be awarded by contract to successful applicants. CPRIT grants are funded on a reimbursement-only basis. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in Section 6. All statutory provisions and relevant administrative rules can be found at http://www.cprit.state.tx.us.

2.4.1. Resubmission Policy

For this mechanism, more than **1 resubmission** is permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PD for a project, or a change of title for a project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission.

2.5. Funding Information

Applicants may request any amount of funding up to a maximum of \$1.5 million in total funding over a maximum of 36 months.

The following estimates may be used as a general guide:

- Primary prevention services only: \$300,000 to \$500,000
- Screening and early detection services, including clinical services: Up to \$1.5 million (projects requesting the maximum should provide comprehensive services, demonstrate broad-based community collaboration, and serve as many people as possible)
- Survivorship services only: \$300,000 to \$500,000

Grant funds may be used to pay for clinical services, navigation services, salary and benefits, project supplies, equipment, costs for outreach and education of populations, and travel of project personnel to project site(s). Requests for funds to support construction, renovation, or any other infrastructure needs or requests to support lobbying will not be approved under this

mechanism. Grantees may request funds for travel for 2 project staff to attend CPRIT's conference.

The budget should be proportional to the number of individuals receiving programs and services, and a significant proportion of funds is expected to be used for program delivery as opposed to program development. In addition, CPRIT seeks to fill gaps in funding rather than replace existing funding, supplant funds that would normally be expended by the applicant's organization, or make up for funding reductions from other sources.

3. KEY DATES

RFA

RFA release April 16, 2015

Application

Online application opens April 30, 2015, 7 AM central time

Application due July 9, 2015, 3 PM central time

Application review September 2015

Award

Award notification November 2015
Anticipated start date December 2015

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

4. APPLICATION SUBMISSION GUIDELINES

4.1. Instructions for Applicants Document

It is imperative that applicants read the accompanying instructions document for this RFA. Requirements may have changed from previous versions.

4.2. Online Application Receipt System

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be considered eligible for evaluation. The PD must create a user account in the system to start and submit an application. The Co-PD, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on April 30, 2015, and must be submitted by 3 PM central time on July 9, 2015. Detailed instructions for submitting an application are in the *Instructions for Applicants* document, posted on CARS. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

4.3. Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via email to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

4.4. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements will be administratively withdrawn without review.

4.4.1. Abstract and Significance (5,000 characters)

Clearly explain the problem(s) to be addressed and the approach(es) to the solution and how the application is responsive to this RFA. In the event that the project is funded, the abstract will be

made public; therefore, no proprietary information should be included in this statement. Initial compliance decisions are based upon review of this statement.

The required abstract format is as follows (use headings as outlined below):

- Need: Include a description of need in the specific service area. Include rates of
 incidence, mortality, and screening in the service area compared to overall Texas rates.
 Describe barriers, plans to overcome these barriers, and the priority population to be
 served.
- Overall Project Strategy: Describe the project and how it will address the identified
 need. Clearly explain what the project is and what it will specifically do, including the
 services to be provided and the process/system for delivery of services and outreach to
 the priority population.
- **Specific Goals:** State specifically the overall goals of the proposed project; include the estimated overall numbers of people (public and/or professionals) to be reached and people (public and/or professionals) to be served.
- **Significance and Impact**: Explain how the proposed project, if successful, will have a unique and major impact on cancer prevention and control for the population proposed to be served and for the state of Texas.

4.4.2. Goals and Objectives (download template)

Goals and objectives must be completed for the initial funded project and for the proposed continuation/expansion project. Enter the goals and objectives for the initial funded project and progress made against each goal and objective in the Goals and Objectives template form. Provide an explanation if goals and objectives were not fully met. Include the number and type of each clinical, education, and navigation service delivered as well as the percent change from the initial baseline. If the baseline was 0, report against the baseline that was established during the initial project.

Enter the goals and objectives for the proposed continuation/expansion project in the CARS text fields. List specific goals and **measurable** objectives for each year of the project. Baseline and method(s) of measurement for the proposed continuation/expansion project are required. Provide

both raw numbers and percent changes for the baseline and target. Applicants must explain plans to establish baseline and describe method(s) of measurement in cases where it has not been defined

4.4.3. Project Timeline

Provide a project timeline for project activities that includes deliverables and dates. Use Years 1, 2, 3, and Months 1, 2, 3, etc., as applicable instead of specific months or years (eg, Year 1, Months 3-5, not 2017, March-May).

4.4.4. Project Plan (15 pages maximum; fewer pages permissible)

The project plan must include information for both the initial funded project and the proposed continuation/expansion project. Please note that a different set of reviewers from those assigned to the previously funded application may evaluate this application. Therefore, applicants should be detailed and clear about the proposed work, even if it is similar to the original project. Also, applicants should make it easy for reviewers to compare the original project with the proposed continuation/expansion project.

4.4.4.1. Initial Project

Introduction: Clearly explain the evidence-based intervention, its purpose, and how it was implemented in the priority population. Describe any adaptations made for the population served. Provide the anticipated end date of the initial project.

Project Results and Outcomes: Address how the need for the evidence-based service was met by describing qualitative results and final outcomes of the project. Quantitative results should be entered in the Goals and Objectives template form (see Section 4.4.2). Describe any barriers or obstacles encountered and strategies used to overcome these. Explain how the project has a unique and major impact on cancer prevention and control.

Integration and Capacity Building: Describe steps taken toward integration and capacity building for components of the projects. (see <u>Integration and Capacity Building</u> of Proposed Project).

Include the roles and effectiveness of key collaborators. If the project director/key staff changed during the project, provide an explanation for the change(s) and impact, if any, on the project.

Dissemination/**Adaptation:** Describe how project results were disseminated or plans for future dissemination of results.

4.4.4.2. Proposed Continuation/Expansion Project

The required project plan format follows. Applicants must use the headings outlined below. Applications not following the required format will be administratively withdrawn.

Introduction: Briefly present the rationale behind the proposed service, emphasizing the critical barriers to current service delivery that will be addressed. Identify the evidence-based service to be implemented for the priority population. Baseline data for the priority population and target service area are required where applicable. Reviewers will be aware of national and state statistics, and these should be used only to compare rates for the proposed service area. Describe the geographic region of the state that the project will serve; maps are appreciated.

Goals and Objectives (optional): Goals and Objectives will be entered in separate fields in CARS and need not be provided in the project plan. However, if desired, goals and objectives may be fully repeated or briefly summarized here.

Components of the Project: Clearly describe the need, delivery method, and evidence base (provide references) for the services as well as anticipated results. Be explicit about the base of evidence and any necessary adaptations for the proposed project. Provide details for any proposed expansion of the project to new geographic areas and/or priority populations. Clearly demonstrate the ability to provide the proposed service and describe how results will be improved over baseline and the ability to reach the priority population. Applicants must also clearly describe plans to ensure access to treatment services should cancer be detected.

Evaluation Strategy: A strong commitment to evaluation of the project is required. Describe the impact on ultimate outcome measures and interim outcome measures as outlined in <u>Section 2.3.3</u>. Describe the plan for outcome measurements, including data collection and management methods, statistical analyses, and anticipated results. Evaluation and reporting of outcomes must be headed by a professional who has demonstrated expertise in the field of program evaluation,

intervention science, cancer screening, and/or behavioral risk reduction. If needed, applicants may want to consider seeking expertise at Texas-based academic cancer centers, schools/programs of public health, prevention research centers, or the like. Applicants should budget accordingly for the evaluation activity and should involve that professional during grant application preparation to ensure, among other things, that the evaluation plan is linked to the proposed goals and objectives.

Organizational Qualifications and Capabilities: Describe the organization and its track record and success in providing programs and services. Describe the role and qualifications of the key collaborators/partners in the project. Include information on the organization's financial stability and viability. To ensure access to preventive services and reporting of services outcomes, applicants should demonstrate that they have provider partnerships and agreements (via memoranda of understanding) or commitments (via letters of commitment) in place.

Integration and Capacity Building: CPRIT funds projects that target the unmet needs not sufficiently covered by other funding sources, and full maintenance of the project may not be feasible. This is especially the case when the project involves the delivery of clinical services. Educational and other less costly interventions may be more readily sustained. Full maintenance of a project, the ability of the grantee's setting or community to continue to deliver the health benefits of the intervention as funded, is not required; however, efforts toward maintenance should be described.

It is expected that steps toward integration and capacity building for components of the project will be taken and plans for such be fully described in the application. *Integration* is defined as the extent the evidence-based intervention is integrated within the culture of the grantee's setting or community through policies and practice. *Capacity building* is any activity (e.g., training, identification of alternative resources, building internal assets) that builds durable resources and enables the grantee's setting or community to continue the delivery of <u>some or all</u> components of the evidence-based intervention.

Elements of integration and capacity building may include, but are not limited to, the following:

 Developing ownership, administrative networks, and formal engagements with stakeholders

- Developing processes for each practice/location to incorporate services into its structure beyond project funding
- Identifying and training of diverse resources (human, financial, material, and technological)
- Implementing policies to improve effectiveness and efficiency (including costeffectiveness) of systems

Dissemination and Scalability (Expansion): Describe how the project lends itself to dissemination to or application by other communities and/or organizations in the state or expansion in the same communities. Describe plans for dissemination of positive and negative project results and outcomes. Dissemination of project results and outcomes, including barriers encountered and successes achieved, is critical to building the evidence base for cancer prevention and control efforts in the state. Dissemination methods may include, but are not limited to, presentations, publications, abstract submissions, and professional journal articles, etc.

4.4.5. People Reached (complete online)

Provide the estimated overall number of people (members of the public and professionals) to be reached by the funded project. The applicant is required to itemize separately the noninteractive education and outreach activities, with estimates, that led to the calculation of the overall estimates provided. Refer to the <u>Appendix</u> for definitions.

4.4.6. People Served (complete online)

Provide the estimated overall number of people (members of the public and professionals) to be served by the funded project. The applicant is required to itemize separately the education, navigation, and clinical activities/services, with estimates, that led to the calculation of the overall estimates provided. Refer to the <u>Appendix</u> for definitions.

4.4.7. References

Provide a concise and relevant list of references cited for the application. The successful applicant will provide referenced evidence and literature support for the proposed services.

4.4.8. Resubmission Summary (if applicable; download template)

Describe the approach to the resubmission and how reviewers' comments were addressed. The summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission; the applicant is not responsible for providing this document.

4.4.9. CPRIT Grants Summary (download template)

Provide a description of the progress or final results of any CPRIT-funded projects of the PD or Co-PD, except for the initial funded project that is the basis for this CCE application, regardless of their connection to this application. Progress for the initial project will be detailed in the Goals and Objectives template form (see Section 4.4.2) and need not be repeated here. Applications that are missing this document and have a PD and/or Co-PD with previous or current CPRIT funds will be administratively withdrawn prior to peer review.

4.4.10. Budget and Justification (complete online)

Provide a brief outline and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, travel, equipment, supplies, contractual expenses, education and outreach expenses, services delivery, and other expenses. CPRIT funds will be distributed on a reimbursement basis.

Applications requesting more than the maximum allowed cost (total costs) as specified in Section 2.5 will be administratively withdrawn.

- **Cost per Person Served:** The cost per person served will be automatically calculated from the total cost of the project divided by the total number of people (both public and professionals) served (refer to the <u>Appendix</u>).
- **Personnel:** The individual salary cap for CPRIT awards is \$200,000 per year. Describe the source of funding for all project personnel where CPRIT funds are not requested.
- **Travel:** PDs and related project staff are expected to attend CPRIT's conference. CPRIT funds may be used to send up to 2 people to the conference.
- **Equipment:** Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does

not need to seek this approval prior to submitting the application. Justification must be provided for why funding for this equipment cannot be found elsewhere; CPRIT funding should not supplant existing funds. Cost sharing of equipment purchases is strongly encouraged.

Services Costs: CPRIT reimburses for services using Medicare reimbursement rates.
 Describe the source of funding for all services where CPRIT funds are not requested.

• Other Expenses

- O Incentives: Use of incentives or positive rewards to change or elicit behavior is allowed; however, incentives may only be used based on strong evidence of their effectiveness for the purpose and in the priority population identified by the applicant. CPRIT will not fund cash incentives. The maximum dollar value allowed for an incentive per person, per activity or session, is \$25.
- Indirect Costs: It is CPRIT's policy not to allow recovery of indirect costs for prevention programs.
- Costs Not Related to Cancer Prevention and Control: CPRIT does not allow recovery of any costs for services not related to cancer (e.g., health physicals, HIV testing).

4.4.11. Current and Pending Support and Sources of Funding (download template)

Describe the funding source and duration of all current and pending support for the proposed project, including a capitalization table that reflects private investors, if any. Information for the initial funded project need not be included.

4.4.12. Biographical Sketches (download template)

The designated PD will be responsible for the overall performance of the funded project and must have relevant education and management experience. The PD/Co-PD(s) must provide a biographical sketch that describes his or her education and training, professional experience, awards and honors, and publications and/or involvement in programs relevant to cancer prevention and/or service delivery.

The evaluation professional must provide a biographical sketch.

Up to 3 additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed 2 pages.

Only biographical sketches will be accepted; do not submit resumes and/or CVs.

4.4.13. Collaborating Organizations (complete online)

List all key participating organizations that will partner with the applicant organization to provide 1 or more components essential to the success of the program (e.g., evaluation, clinical services, recruitment to screening).

4.4.14. Letters of Commitment

Applicants should provide letters of commitment and/or memoranda of understanding from community organizations, key faculty, or any other component essential to the success of the program.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively withdrawn without review.

5. APPLICATION REVIEW

5.1. Review Process Overview

All eligible applications will be reviewed using a 2-stage peer review process: (1) evaluation of applications by peer review panels and (2) prioritization of grant applications by the Prevention Review Council. In the first stage, applications will be evaluated by an independent review panel using the criteria listed below. In the second stage, applications judged to be meritorious by review panels will be evaluated by the Prevention Review Council and recommended for funding based on comparisons with applications from all of the review panels and programmatic priorities. Programmatic considerations may include, but are not limited to, geographic distribution, cancer type, population served, and type of program or service. The scores are only 1 factor considered during programmatic review. At the programmatic level of review priority will be given to proposed projects that target geographic regions of the state or population subgroups that are not well represented in the current CPRIT Prevention project portfolio.

Applications approved by the Prevention Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

Each stage of application review is conducted confidentially, and all CPRIT Peer Review Panel members, Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Peer Review Panel members and Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer Review Panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee Member, a PIC Member, a Review Panel member, or a Review Council member. Applicants should note that the CPRIT PIC Committee comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the

particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

5.2. Review Criteria

Peer review of applications will be based on primary (scored) criteria and secondary (unscored) criteria, identified below. Review panels consisting of experts in the field and advocates will evaluate and score each primary criterion and subsequently assign an overall score that reflects an overall assessment of the application. The overall evaluation score will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application and responsiveness to the RFA priorities.

5.2.1. Primary Evaluation Criteria

Impact

- Do the proposed services address an important problem or need in cancer prevention and control? Will the proposed outcomes have a significant impact on cancer incidence, morbidity, and/or mortality?
- Will the project reach and serve an appropriate number of people based on the budget allocated to providing services and the cost of providing services?
- Does the proposed continuation/expansion project build on its initial results (baseline) and continue to demonstrate creativity, ingenuity, resourcefulness, or imagination? Does it go beyond the initial project to address what the applicant has learned or explore new partnerships, new audiences, or improvements to systems?
- Does the program address known gaps in prevention services and avoid duplication of effort?

Previous Project Performance

• Does the proposed continuation project demonstrate a high likelihood of success based on the initial project's results and outcomes?

• Does the applicant provide evidence of compelling project progress of the already-funded project? If not, has the applicant addressed obstacles and strategies to overcome those obstacles?

Project Strategy and Feasibility

- Does the proposed project provide prevention interventions or services specified in the RFA?
- Are the overall program approach, strategy, and design clearly described and supported by established theory and practice? Are the base of evidence and any necessary adaptations clearly defined and referenced?
- Are the proposed objectives and activities feasible within the duration of the award? Has the applicant convincingly demonstrated the short- and long-term impacts of the project?
- Are possible barriers addressed and approaches for overcoming them proposed?
- Are the priority population and culturally appropriate methods to reach the priority population clearly described? If applicable, does the application demonstrate the availability of resources and expertise to provide case management, including followup for abnormal results and access to treatment?
- Does the program leverage partners and resources to maximize the reach of the services proposed? Does the program leverage and complement other state, federal, and nonprofit grants?

Outcomes Evaluation

- Are specific goals and measurable objectives for each year of the project listed for both the initial project and the proposed continuation project? Does the applicant provide the baseline and results or method(s) of measurement?
- Are the proposed outcome measures appropriate for the services provided, and are the expected changes clinically significant?
- Does the application provide a clear and appropriate plan for data collection and management, statistical analyses, and interpretation of results to follow, measure, and report on the project's outcomes?

- If an evidence-based intervention is being adapted in a population where it has not been tried/tested, are plans for evaluation of barriers, effectiveness, and fidelity to the model described?
- Is the qualitative analysis of planned policy or system changes described?

Organizational Qualifications and Capabilities

- Do the organization and its collaborators/partners demonstrate the ability to provide the proposed preventive services? Does the described role of each collaborating organization make it clear that each organization adds value to the project and is committed to working together to implement the project?
- Have the appropriate personnel been recruited to implement, evaluate, and complete the project?
- Is the organization structurally and financially stable and viable?

Integration and Capacity Building

- Does the applicant describe steps that will be taken and components of the project that will be integrated into the organization through policies and practices?
- Does the applicant describe steps that will be taken or components of the project that will remain (e.g., trained personnel, identification of alternative resources, building internal assets) to continue the delivery of <u>some or all</u> components of the evidence-based intervention once CPRIT funding ends?

5.2.2. Secondary Evaluation Criteria

Budget

- Is the budget appropriate and reasonable for the scope and services of the proposed work?
- Is the cost per person served appropriate and reasonable?
- Is the proportion of the funds allocated for direct services reasonable?
- Is the project a good investment of Texas public funds?

Dissemination and Scalability (Expansion)

- Are plans for dissemination of the project's results and outcomes, including barriers encountered and successes achieved, clearly described?
- Does the applicant clearly describe how the project lends itself to dissemination to or adaptation and application by other communities and/or organizations in the state or expansion in the same communities?

6. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at http://www.cprit.state.tx.us. Applicants are advised to review CPRIT's Administrative Rules regarding contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires the PD of the award to submit quarterly, annual, and final progress reports. These reports summarize the progress made toward project goals and address plans for the upcoming year and performance during the previous year(s). In addition, quarterly fiscal

reporting and reporting on selected metrics will be required per the instructions to award

recipients. Failure to provide timely and complete reports may waive reimbursement of grant

award costs and may result in the termination of the award contract.

7. **CONTACT INFORMATION**

7.1. **HelpDesk**

HelpDesk support is available for questions regarding user registration and online submission of

applications. Queries submitted via email will be answered within 1 business day. HelpDesk

staff are not in a position to answer questions regarding the scope and focus of applications.

Before contacting the HelpDesk, please refer to the *Instructions for Applicants* document (posted

by April 30, 2015), which provides a step-by-step guide to using CARS.

Dates of operation: April 30, 2015, to July 9, 2015 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time

Wednesday, 8 AM to 4 PM central time

Tel:

866-941-7146

Email:

Help@CPRITGrants.org

7.2. **Program Questions**

Questions regarding the CPRIT Prevention program, including questions regarding this or any

other funding opportunity, should be directed to the CPRIT Prevention Program Office.

Tel:

512-305-8422

Email:

Help@CPRITGrants.org

Website:

www.cprit.state.tx.us

8. RESOURCES

- The Texas Cancer Registry: http://www.dshs.state.tx.us/tcr
- The Community Guide http://www.thecommunityguide.org/index.html
- Cancer Control P.L.A.N.E.T. http://cancercontrolplanet.cancer.gov
- Guide to Clinical Preventive Services: *Recommendations of the U.S. Preventive Services Task Force*. http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/
- Centers for Disease Control and Prevention: The Program Sustainability Assessment
 Tool: A New Instrument for Public Health Programs
 http://www.cdc.gov/pcd/issues/2014/13_0184.htm
- Centers for Disease Control and Prevention: *Using the Program Sustainability Tool to Assess and Plan for Sustainability* http://www.cdc.gov/pcd/issues/2014/13 0185.htm
- Moore DE. A Framework for Outcomes Evaluation in the Continuing Professional Development of Physicians. In: Davis D, Barnes BE, Fox R, eds. The Continuing Professional Development of Physicians: From Research to Practice. Chicago, Ill: American Medical Association; 2003.
- Centers for Disease Control and Prevention. Distinguishing Public Health Research and Public Health Nonresearch. http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf.
- Brownson, RC, Colditz GA, and Proctor, EK (Editors), Dissemination and Implementation Research in Health: Translating Science to Practice. Oxford University Press, March 2012.

9. REFERENCES

- 1. http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm
- 2. Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas

 Department of State Health Services: http://www.dshs.state.tx.us/tcr/default.shtm

10. APPENDIX: KEY TERMS

- Activities: A listing of the "who, what, when, where, and how" for each objective that will be accomplished.
- Capacity Building: Any activity (e.g., training, identification of alternative resources, building internal assets) that builds durable resources and enables the grantee's setting or community to continue the delivery of some or all components of the evidence-based intervention.
- Clinical Services: Number of clinical services such as screenings, diagnostic tests, vaccinations, counseling sessions, or other evidence-based preventive services delivered by a health care practitioner in an office, clinic, or health care system. Other examples include genetic testing or assessments, physical rehabilitation, tobacco cessation counseling or nicotine replacement therapy, case management, primary prevention clinical assessments, and family history screening.
- Education Service: Number of evidence-based, culturally appropriate cancer prevention and control education and outreach services delivered to the public and to health care professionals. Examples include education or training sessions (group or individual), focus groups, and knowledge assessments.
- Evidence-Based Program: A program that is validated by some form of documented research or applied evidence. CPRIT's website provides links to resources for evidence-based strategies, programs, and clinical recommendations for cancer prevention and control. To access this information, visit
 http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control.
- Goals: Broad statements of general purpose to guide planning. Goals should be few in number and focus on aspects of highest importance to the project.
- **Integration**: The extent the evidence-based intervention is integrated within the culture of the grantee's setting or community through policies and practice.
- Navigation Services: Number of unique activities/services that offer assistance to help overcome health care system barriers in a timely and informative manner and facilitate cancer screening and diagnosis to improve health care access and outcomes. Examples

- include patient reminders, transportation assistance, and appointment scheduling assistance.
- **Objectives:** Specific, **measurable**, actionable, realistic, and timely projections for outputs and outcomes. Example: "Increase screening service provision in X population from Y% to Z% by 20xx." Baseline data for the priority population must be included as part of each objective.
- **People Reached:** Number of members of the public and/or professionals reached via noninteractive public or professional education and outreach activities, such as mass media efforts, brochure distribution, public service announcements, newsletters, and journals. This category includes individuals who would be reached through activities that are directly funded by CPRIT as well as individuals who would be reached through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project.
- **People Served:** Number of members of the public and/or professionals served via direct, interactive public or professional education, outreach, training, navigation service delivery, or clinical service delivery, such as live educational and/or training sessions, vaccine administration, screening, diagnostics, case management/navigation services, and physician consults. This category includes individuals who would be served through activities that are directly funded by CPRIT as well as individuals who would be served through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project (e.g., X people screened for cervical cancer after referral to Y indigent care program as a result of CPRIT-funded navigation services performed by the project).

Third Party Observer Reports



CPRIT Peer Review Meeting Observation Report

Report #2015-09-21/22-PRE

Program Name: Prevention

Panel Name: FY16.1 Prevention Peer Review Panel - 1

Panel Date: September 21, 2015 to September 22, 2015

Report Date: September 30, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Peer Review Panel-1 peer review of applications for FY16 funding. The meeting was co-chaired by Ross Brownson and Nancy Lee and held at the Hyatt Regency in Dallas TX on September 21 through September 22, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Prevention Peer Review Panel-1 panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and co-chaired by Ross Brownson and Nancy Lee on September 21 through September 22, 2015.

The independent observer noted the following during our observation:

- Sixteen applications were discussed within the Prevention Peer Review Meeting Panel to determine
 which grants would receive CPRIT funding.
- Eleven peer review panelists, two advocate reviewers, four CPRIT staff members and five SRA
 employees were present on September 21, 2015. Eleven peer review panelists, two advocate reviewers,
 three CPRIT staff members and five SRA employees were present on September 22, 2015.
- Eight conflicts of interest were identified prior to or during the meeting. Applications for seven
 conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest either
 left the room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Prevention Review Council Meeting Observation Report

Report #2015-10-23-PREV

Program Name: Prevention

Panel Name: FY16.1 Prevention Review Council

Programmatic Review

Panel Date: October 23, 2015 Report Date: October 29, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Review Council Programmatic Review peer review of applications for FY16 funding. The meeting was chaired by Stephen Wyatt and held via teleconference on October 23, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Prevention Review Council Programmatic Review held via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Stephen Wyatt on October 23, 2015.

The independent observer noted the following during our observation:

- Sixteen applications were discussed within the Prevention Review Council Meeting to determine which
 grants would receive CPRIT funding.
- Three peer review panelists, two CPRIT staff members and one SRA employee were present for the meeting.
- One conflict of interest was identified prior to or during the meeting. Applications for one conflict was
 discussed during the peer review panel. The reviewer with the conflict of interest either left the room
 or did not participate telephonically and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Prevention Cycle 16.1 Applications (Prevention Cycle 16.1 Awards Announced at November 19, 2015, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Prevention Cycle 16.1 include Cancer Prevention Promotion and Navigation to Clinical Services, Competitive Continuation/Expansion—Evidence-Based Cancer Prevention Services, Evidence-Based Cancer Prevention Services, Evidence-Based Cancer Prevention Services - Colorectal Cancer Prevention Coalition, and Dissemination of CPRIT-Funded Cancer Prevention and Control Interventions. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted								
Applica	Applications considered by the PIC and Oversight Committee										
PP160023	Sauter, Edward	The University of Texas Health Center at Tyler	Schwartz, Randy; Cole, Kirk								
PP160027	Foxhall, Lewis	The University of Texas M.D. Anderson Cancer Center	Vanderpool, Robin; Cole, Kirk								
PP160042	Parra-Medinca, Deborah	The University of Texas Health Science Center at San Antonio	Vanderpool, Robin								
PP160046	Cuccaro, Paula	The University of Texas Health Science Center at Houston	Vanderpool, Robin								
PP160047	Savas, Lara	The University of Texas Health Science Center at Houston	Brownson, Ross								
PP160048	Bolin, Jane	Texas A&M University System Health Science Center	Escabedo, Luis; Cole, Kirk								
PP160051	Fernandez, Maria	Texas A&M University System	Cole, Kirk								

Application ID	Applicant	Institution	Conflict Noted
		Health Science	
		Center	
Applications Not	Recommended for PIC	C or Oversight Commit	tee Consideration
PP160026	Handal, Gilbert	Texas Tech	Escobedo, Luis
		University Health	
		Sciences Center at El	
		Paso	
PP160043	Gonzalez, Hector	City of Laredo Health	Escobedo, Luis
		Department	

De-Identified Overall Evaluation Scores

Competitive Continuation/Expansion—Evidence-Based Cancer Prevention Services

Prevention Cycle 16.1

Application ID	Final Overall Evaluation Score
PP160049*	1.9
PP160033 ¹	2.4
PP160011*	2.7
PP160047*	2.7
PP160036*	3.3
aa	4.4

See "Final Overall Evaluation Scores and Rank Order Scores" section for explanation by Prevention Review Council of recommendation out of score order.

¹ PP160033 was recommended by the Prevention Review Council and deferred to a future Program Integration Committee meeting by the Program Integration Committee members.

^{*=}Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

Pete Geren
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to pgcprit@sidrichardson.org

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Mr. Roberts and Mr. Geren,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for CPRIT Prevention grant awards. The applicants on the attached list of submitted proposals responded to CPRIT requests for applications (RFA) released for the first review cycle of FY2016. These recommendations reflect 50+ hours of work by individual reviewers and include panel discussion of the applicants' proposals, in addition to the PRC's programmatic review.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are provided for each grant application. The PRC did not make changes to the goals, timelines, or project objectives requested by the applicants. When the PRC did not follow the rank ordered scores in developing its recommended funding order a justification, based upon established programmatic priorities outlined in the RFAs, is provided.

The projected funding available for this fiscal year is \$27,965,885. However, the recent interpretation that annual prevention program funding is 10% of the CPRIT awarded dollars within a fiscal year could impact the dollars available. With the second funding cycle for the fiscal year underway, the PRC opted for a conservative approach to its recommendations for this cycle. Recommendations are provided at two levels: (1) initially fund 12 projects totaling an estimated \$13,247,742 and (2) depending upon the availability of funds later in the fiscal year, fund an additional 2 projects (PP160046 and PP160033 totaling \$2,999,657).

Our recommendations meet the PRC's standards for grant award funding of projects that are evidence-based, deliver programs or services to underserved populations, and focus on primary, secondary or tertiary prevention. In making these recommendations the PRC also considered the available funding, the composition of the current portfolio, and the programmatic priorities in the RFA which include potential for impact and return on investment, geographic distribution, cancer type and type of program. All of the recommended grants address one or more of the Prevention Program priorities.

Sincerely,

Stephen W. Wyatt, DMD, MPH Chair, CPRIT Prevention Review Council

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP160049	CCE- EBP	Expansion of a comprehensive cervical cancer screening program for medically underserved women in Harris County	Anderson, Matthew L	Baylor College of Medicine	\$1,500,000	1.9			1	
PP160047	CCE- EBP	A community based program to increase breast and cervical cancer screening and HPV vaccination to reduce the impact of breast and certical cancer among Latinas	Savas, Lara S	The University of Texas Health Science Center at Houston	\$1,387,005	2.7	Steps that will be taken to assess actual # of screenings and vaccinations for participants in educational sessions are not explained. It appears that only women completing the surveys will be followed. Evaluation of outcomes for all participants is not provided, only provided for women completing surveys. Budget is unclear about number of screenings that will be paid for; number of financially supported	Changes not recommended-PRC reviewed peer review comments and determined those comments did NOT impact decision to recommend or impact rank order	2	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							screening isn't clearly stated.			
PP160042	EBP	Using Best Practices to Promote HPV vaccination in Rural Primary Care Settings	Parra- Medina, Deborah	The University of Texas Health Science Center at San Antonio	\$1,295,493	2.8	Outcomes evaluation doesn't have baseline and % increase noted. A highly intensive program is being implemented and the high cost is a barrier. If the cost is reduced, the applicability of the proposed approach may be enhanced. Reviewers would like the applicants to clarify why the increase in the budget from the previous grant to this grant. Why has the per person	changes not recommended- PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	3	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							cost increased so much?			
PP160032	PN	Family Health History-based Colorectal Cancer Prevention and Navigation to Clinical Services among Uninsured Chinese Americans in Texas	Chen, Lei- Shih	Texas A&M University	\$399,993	3.0	Findings from this study should be applied to follow-up treatment for the participants. Plans for this are lacking and should be provided.	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	4	
PP160056	PN	REACH Rural Education and Awareness for Community Health	Hoelscher, Bill	Coastal Bend Wellness Foundatio n	\$379,698	3.0	Should be clarified that \$25 gift card is not being offered to change the behavior of the participants.	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	5	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP160010	ЕВР	Maximizing opportunities for HPV vaccination in the Golden Triangle	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	\$1,409,909	3.1	Ask applicants why they do not plan to vaccinate young adults on college campuses. In addition, students could be used to help with recruitment	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	6	
PP160048	DI	Training CHWs for More Effective Cancer Education and Navigation	Bolin, Jane N	Texas A&M University System Health Science Center	\$300,000	3.1			7	
PP160023	EBP- CRC	Optimizing Colorectal Cancer Screening in East Texas	Sauter, Edward	The University of Texas Health Center at Tyler	\$2,299,753	3.3	Recommendation was made in previous application that providing FIT isn't evidence-based for people who are at significant risk for CRC; this isn't consistent with ACS guidelines. Ask how they came up with \$275/colonoscopy	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	8	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP160036	CCE- EBP	Establishing a Comprehensiv e Cancer Prevention and Support Program within Asian American Communities in Houston and Austin Areas of Texas	Sun, Helen	Light and Salt Associatio n	\$1,101,986	3.3	Request that the applicant provides a leadership plan that includes input from the three communities being targeted: Vietnames, Korean, and Filipino	changes not recommended-PRC reveiwed peer review comments and determined they did not impact decision to recommend or impact rank order	9	
PP160027	EBP	Improving Service Delivery to Cancer Survivors in Primary Care Settings	Foxhall, Lewis E	The University of Texas M. D. Anderson Cancer Center	\$1,374,127	3.5	Not clear how project will add to what is already happening in clinic. This is a large, complex project and not clear how it will be managed on a daily basis. Budget is weak and justification for some of the positions is lacking	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	10	Recommende d out of score order above one with higher score due to ROI and cancer type
PP160051	DI	Dissemination of an Evidence- Based HPV Vaccination Intervention in Community and Clinical Settings	Fernandez , Maria E	The University of Texas Health Science Center at Houston	\$299,778	3.6	List of current awards doesn't specify PD participation; it should be verified that PD isn't overcommitted. Budget seems somewhat personnel heavy and accounts for a	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	11	Recommende d out of score order above one with higher score due to type of program

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							large majority of voerall costs; careful review of personnel and their exact roles and responsibilities and whether or not any of the services are duplicative may be warranted.			
PP160011	CCE- EBP	GRACIAS Texas: Genetic Risk Assessment for Cancer in All South Texas	Tomlinson , Gail E	The University of Texas Health Science Center at San Antonio	\$1,500,000	2.7			12	Recommende d but ranked out of score order due to 1) ROI may be limited; large numbers need to be screened to identify at risk pop.
PP160046	EBP	Using social marketing and mobile school-based vaccination clinics to increase HPV vaccination uptake in highrisk geographic areas	Cuccaro, Paula	The University of Texas Health Science Center at Houston	\$1,499,668	2.2			13	Recommende d but out of score order due to 1) geography- several HPV grants in Harris county, 2) ROI-costs for education vs services

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP160033	CCE- EBP	Increasing cancer control behaviors among the underserved: A collaboration with Texas 2-1-1 programs	Fernandez , Maria E	The University of Texas Health Science Center at Houston	\$1,499,989	2.4			14	Recommende d but out of score order due to 1) geography- several HPV grants in Harris county, 2) cancer type- availabilty of breast and cervical services 3) ROI-costs for education vs services
				Initial funding (Rank #1- 12)	\$13,247,74 2					
				(Rank #13+14) 2nd	\$2,999,657 \$16,247,39					
				funding	9					



CEO Affidavit Supporting Information

FY 2016—Cycle 1
Dissemination of CPRIT-Funded Cancer Prevention and
Control Interventions

Request for Applications



REQUEST FOR APPLICATIONS RFA P-16-DI-1

Dissemination of CPRIT-Funded Cancer Control Interventions

Please also refer to the "Instructions for Applicants" document, which will be posted April 30, 2015

Application Receipt Opening Date: April 30, 2015

Application Receipt Closing Date: July 9, 2015

FY 2016

Fiscal Year Award Period

September 1, 2015-August 31, 2016

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RFA VERSION HISTORY

Rev 4/16/15 RFA release

1. ABOUT CPRIT

The state of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the state of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Prevention Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The Prevention Program's principles and priorities will also guide CPRIT staff and the Prevention Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

Established Principles:

- Fund evidence-based interventions and their dissemination
- Support the prevention continuum of primary, secondary and tertiary (includes survivorship) prevention interventions

Prevention Program Priorities

- Prioritize populations and geographic areas of greatest need, greatest potential for impact
- Focus on underserved populations
- Increase targeting of preventive efforts to areas where significant disparities in cancer incidence or mortality in the state exist

2. FUNDING OPPORTUNITY DESCRIPTION

2.1. Summary

The ultimate goals of the CPRIT Prevention Program are to reduce overall cancer incidence and mortality and to improve the lives of individuals who have survived or are living with cancer. The ability to reduce cancer death rates depends in part on the application of currently available evidence-based technologies and strategies. CPRIT will foster the primary, secondary, and tertiary prevention of cancer in Texas by providing financial support for a wide variety of evidence-based risk reduction, early detection, and survivorship interventions.

The **Dissemination of CPRIT-Funded Cancer Control Interventions (DI)** award mechanism seeks to fund programs that facilitate the dissemination and implementation of successful CPRIT funded, evidence-based cancer prevention and control interventions across Texas. **This award mechanism is open only to previously or currently funded CPRIT projects.**

The proposed program should describe and package strategies or approaches to introduce, modify, and implement previously funded CPRIT evidence-based cancer prevention and control interventions for dissemination to other settings and populations in the state. To be eligible, the applicant should be in a position to develop 1 or more "products" based on the results of the CPRIT-funded intervention. The proposed projects should also identify and assist others prepare to implement the intervention and/or prepare to apply for grant funding.

2.2. Project Objectives

CPRIT seeks to fund projects that will provide 1 or more of the following:

- Dissemination of tools or models to public health professionals, health care practitioners, health planners, policymakers, and advocacy groups;
- Dissemination of materials or information about an intervention to broader settings/systems; and
- Dissemination or scaling up of best practices (infrastructure and tools) and evidence-based interventions for implementation (i.e., implementation guides).

2.3. Award Description

The **Dissemination of CPRIT funded Cancer Control Interventions** RFA solicits applications from current or previously funded CPRIT projects that have demonstrated exemplary success and have materials, policies, other resources that have been successfully implemented and evaluated and could be scaled up and/or applied to other systems and settings.

The Center for Research in Implementation Science and Prevention website (http://www.dissemination-implementation.org/measures.aspx) defines active and passive dissemination strategies as follows: "Dissemination strategies describe mechanisms and approaches that are used to communicate and spread information about interventions to targeted users. Dissemination strategies are concerned with the packaging of the information about the intervention and the communication channels that are used to reach potential adopters and target audience. Passive dissemination strategies include mass mailings, publication of information including practice guidelines, and untargeted presentations to heterogeneous groups. Active dissemination strategies include hands on technical assistance, replication guides, point-of-decision prompts for use, and mass media campaigns. It is consistently stated in the literature that dissemination strategies are necessary but not sufficient to ensure wide-spread use of an intervention."

Adopters will need to employ implementation strategies to replicate or adapt projects to their settings or populations. Implementation strategies are described as the systematic processes, activities, and resources that are used to integrate interventions into usual settings. Core implementation components or implementation drivers can be staff selection, preservice and inservice training, ongoing consultation and coaching, staff and program evaluation, facilitative administrative support, and systems interventions. (See http://www.dissemination-implementation.org/measures.aspx)

This award will support both passive and active dissemination strategies but must include <u>2 or more active</u> dissemination strategies. This award will also support implementation strategies in the form of technical assistance, coaching, and consultation within the time period of the grant. CPRIT recognizes there are limits to the amount of technical assistance or coaching that can be accomplished within the grant period; however, priority will be given to those projects that identify and assist potential adopters prepare to implement the intervention and/or prepare to

apply for grant funding. Examples of active dissemination strategies and implementation strategies include the following:

Tools/models

- Toolkits with materials, sample policies, and procedures for implementation of CPRIT funded programs;
- Interactive websites that provide future adopters with key information on how to implement CPRIT-related interventions;
- Approaches for dissemination of findings via nontraditional channels (eg, social media);
- User-friendly summaries; short issue or policy briefs that tell a story for decision-makers based on CPRIT findings;
- Brief, user-friendly case studies from program developers and recipients to illustrate key issues

<u>Implementation guides</u>

- Targeted communication materials emphasizing how to apply them to different populations, systems, settings;
- Step-by step implementation guides on how to translate an evidence-based intervention/program to broader settings, including guidelines for retaining core elements of the interventions or programs while offering suggested adaptations for the elements that would enhance the adoption and sustainability of the programs in different populations, setting or circumstances. (see Partnership for Prevention examples: https://www.prevent.org/Action-Guides/The-Community-Health-Promotion-Handbook.aspx)

Training/Technical assistance

 Provision of training and technical assistance to guide adopters in developing their plans to adapt, refine, and implement their projects.

In addition, proposed materials should include a discussion of barriers to dissemination, a description of personnel and necessary resources to overcome barriers to implementation, a

description of expected outcomes, evaluation strategies with a sample evaluation plan and tools (if applicable), and suggestions or plan for project sustainability, capacity building or integration.

Under this RFA, CPRIT will not consider the following:

- Proposals to disseminate projects not previously or currently funded by CPRIT.
- Projects involving prevention/intervention research. Applicants interested in prevention research should review CPRIT's research RFAs (available at http://www.cprit.state.tx.us).

2.3.1. Priorities

Priority will be given to proposals to disseminate and replicate projects that when implemented can address the following program priorities set by the CPRIT Oversight Committee:

- Prioritize populations and geographic areas of greatest need, greatest potential for impact
- Focus on underserved populations (see priority populations)
- Increase targeting of preventive efforts to areas where significant disparities in cancer incidence and mortality in the state exist. (see <u>Section 2.3.2</u>)

Priority Populations:

Priority populations are subgroups that are disproportionately affected by cancer.

- Underinsured and uninsured individuals
- Geographically or culturally isolated populations
- Medically unserved or underserved populations
- Populations with low health literacy skills
- Geographic regions or populations of the state with higher prevalence of cancer risk factors (e.g., obesity, tobacco use, alcohol misuse, unhealthy eating, sedentary lifestyle)
- Racial, ethnic, and cultural minority populations
- Other populations with low screening rates, high incidence rates, and high mortality rates, focusing on individuals never before screened or who are significantly out of compliance with nationally recommended screening guidelines

2.3.2. Specific Areas of Emphasis

CPRIT is interested in applications focused on the following:

A. Primary Prevention

Tobacco Prevention and Control

- Decreasing tobacco use in areas of the state that have higher smoking rates per capita than other areas of the state.
 - Health Service Regions (HSRs) 2, 4, and 5 have significantly higher tobacco use among adults than in other regions of the state. For more information about maps of Health Service Regions, please visit http://www.dshs.state.tx.us/regions/state.shtm.

HPV Vaccination

- Increasing access to, delivery of, and completion of the HPV vaccine regimen to males and females through evidence-based intervention efforts.
 - HPV vaccine completion rates are low (15% for males and 39% for females)
 across the state compared to the CDC goals of 75% completion rates.¹

Liver Cancer

- Decreasing disparities in incidence and mortality rates for hepatocellular cancer (HCC).
 - HCC incidence is significantly higher in Texas Hispanics, blacks, and Asian/Pacific Islanders than in non-Hispanic whites.²
 - Significantly higher HCC rates in Texas Hispanics versus the United States are driven by very high rates among Hispanics in South Texas.²
 - o Males have significantly higher incidence and mortality rates than females.²
 - Age at diagnosis is shifting toward younger patients, both in Texas and United States.²

B. Secondary Prevention - Screening and Early Detection Services

Colorectal Cancer

- Increasing screening/detection rates in HSRs 1 through 6 and HSR 9.
 - The highest rates of cancer incidence mortality are found in these regions of Texas²
- Decreasing disparities in incidence and mortality rates of colorectal cancer for racial/ethnic populations and rural communities.
 - African Americans have the highest incidence and mortality rates, followed by non-Hispanic whites and Hispanics.²
- Decreasing incidence and mortality rates in rural counties.
 - Incidence and mortality rates are higher in rural counties compared to urban counties.²

Cervical Cancer

- Increasing screening/detection rates for women in Texas-Mexico border counties.
 - Women in these counties have a 30% higher cervical cancer mortality rate than women in nonborder counties.²
- Decreasing disparities in racial/ethnic populations.
 - Hispanics have the highest incidence rates, while African Americans have the highest mortality rates.²
- Reaching women never before screened.

Breast Cancer

- Increasing screening/detection rates in rural and medically underserved areas of the state.
- Reaching women never before screened.

Data on cancer incidence and mortality are provided by the Texas Cancer Registry². For more information about cancer in Texas, visit CPRIT's website at

http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control or visit the Texas Cancer Registry site at http://www.dshs.state.tx.us/tcr/

C. Tertiary Prevention - Survivorship Services

- Preventing secondary cancers and recurrence of cancer
- Managing the after effects of cancer and treatment to maximize quality of life and number of years of healthy life
- Minimizing preventable pain, disability, and psychosocial distress

Applicants proposing survivorship projects may address people with any type of cancer.

2.3.3. Outcome Metrics

The applicant is required to describe how the goals and objectives for each year of the project as well as the final outcomes will be measured. The applicant should provide a clear and appropriate plan for data collection and interpretation of results to report against goals and objectives.

Reporting Requirements

Funded projects are required to report quantitative output and outcome metrics (as appropriate for each project) through the submission of quarterly progress reports, annual reports, and a final report.

- Quarterly progress report sections include, but are not limited to the following:
 - Narrative on project progress, including the number and description of all active and passive dissemination and implementation activities undertaken.
- Annual and Final progress report sections include, but are not limited to the following:
 - o Key accomplishments, including discussion of barriers to dissemination;
 - o Progress against goals and objectives;
 - o Materials produced;
 - o Presentations, publications, etc.

2.4. Eligibility

• The applicant must be a Texas-based entity, such as a community-based organization, health institution, government organization, public or private company, college or university, or academic health institution.

- The designated Program Director (PD) will be responsible for the overall performance of the funded project. The PD must have relevant education and management experience and must reside in Texas during the project performance time.
- The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant may submit more than 1 application, but each application must be for distinctly different projects without overlap in the projects. Applicants who do not meet this criterion will have all applications administratively withdrawn without peer review.
- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Subcontracting and collaborating organizations may include public, notfor-profit, and for-profit entities. Such entities may be located outside of the state of Texas, but non—Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant organization is eligible to receive a grant award only if the applicant certifies that the applicant organization, including the PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), have not made and will not make a contribution to CPRIT or to any foundation created to benefit CPRIT.
- The applicant must report whether the applicant organization, the PD, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, (whether slated to receive salary or compensation under the grant award or not), are currently ineligible to receive federal grant funds because of scientific misconduct or fraud or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. CPRIT grants are funded on a reimbursement-only basis. Certain contractual requirements are mandated by

Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in Section 6. All statutory provisions and relevant administrative rules can be found at http://www.cprit.state.tx.us.

2.5. Funding Information

Applicants may request any amount of funding up to a maximum of \$300,000 in total funding over a maximum of 24 months. Grant funds may be used to pay for salary and benefits, project supplies, equipment, costs for outreach and education, and travel of project personnel to project site(s). Requests for funds to support construction, renovation, or any other infrastructure needs or requests to support lobbying will not be approved under this mechanism. Grantees may request funds for travel for 2 project staff to attend CPRIT's conference.

The budget should be well justified. In addition, CPRIT seeks to fill gaps in funding rather than replace existing funding, supplant funds that would normally be expended by the applicant's organization or make up for funding reductions from other sources.

3. KEY DATES

RFA

RFA release April 16, 2015

Application

Online application opens April 30, 2015, 7 AM central time

Application due July 9, 2015, 3 PM central time

Application review September 2015

Award

Award notification November 2015
Anticipated start date December 2015

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

4. APPLICATION SUBMISSION GUIDELINES

4.1. Instructions for Applicants document

It is imperative that applicants read the accompanying instructions document for this RFA (https://CPRITGrants.org). Requirements may have changed from previous versions.

4.2. Online Application Receipt System

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be considered eligible for evaluation. The PD must create a user account in the system to start and submit an application. The Co-PD, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on April 30, 2015, and must be submitted by 3PM central time on July 9, 2015. Detailed instructions for submitting an application are in the *Instructions for Applicants* document, posted on CARS. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

4.3. Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via email to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

4.4. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Refer to the *Instructions for Applicants* document for details. Submissions that are missing 1 or more components or do not meet the eligibility requirements will be administratively withdrawn without review.

4.4.1. Abstract and Significance (5,000 characters)

Clearly explain the problem(s) to be addressed, the approach(es) to the solution, and how the application is responsive to this RFA. In the event that the project is funded, the abstract will be made public; therefore no proprietary information should be included in this statement. Initial compliance decisions are based in part upon review of this statement.

The required abstract format is as follows (use headings as outlined below):

- **Need:** Include a description of need for the proposed project.
- Overall Project Strategy: Describe the project and how it will address the identified need.
- Specific Goals: State specifically the overall goals of the proposed project.
- **Innovation:** Describe the creative components of the proposed project.
- **Significance and Impact:** Explain how the proposed project, if successful, will have a unique and major impact on cancer prevention and control and for the state of Texas.

4.4.2. Goals and Objectives

List specific goals and **measurable** objectives for each year of the project. A baseline and method(s) of measurement are required for each objective.

4.4.3. Project Timeline

Provide a project timeline for project activities that includes deliverables and dates. Use Years 1, 2, 3 and months 1,2,3, etc., as applicable instead of specific months or years (e.g., Year 1, Months 3-5, not 2017, March – May).

4.4.4. Project Plan (15 pages maximum; fewer pages permissible)

The required project plan format follows. Applicants must use the headings outlined below. Applications not following the required format will be administratively withdrawn.

Background: Describe the project to be disseminated and how and why it lends itself to replication and scalability. Describe the effectiveness of the intervention that is being proposed for replication/dissemination and the expected short- and long-term impacts of the project. Describe why this project is needed, creative, or unique.

Goals and Objectives (optional): Goals and Objectives will be entered in separate fields in CARS and need not be provided in the project plan. However, if desired, goals and objectives may be fully repeated or briefly summarized here.

Components of the Project: Clearly describe the data demonstrating success of the CPRIT-funded project that justifies dissemination. Describe components of the proposed dissemination project and the dissemination approach, strategy (e.g., passive and active dissemination and implementation strategies), and the products being designed or packaged. Clearly describe the established theory and practice that support the proposed approach or strategy. Describe parameters of the CPRIT-funded project that may affect its dissemination and replication such as target audience for which it was designed, specialized resources that may be needed, or geographic considerations.

Evaluation Strategy: Describe the evaluation plan and methodology to assess dissemination effectiveness (e.g., include short and intermediate impact of dissemination activities, knowledge and behavior change among the audience likely to adopt the project). Describe a clear and appropriate plan for data collection and interpretation of results to report against goals and objectives. If needed, applicants may want to consider seeking expertise at Texasbased academic cancer centers, schools/programs of public health, prevention research centers, or the like. Applicants should budget accordingly for the evaluation activity and should ensure, among other things, that the evaluation plan is linked to the proposed goals and objectives.

Organizational Qualifications and Capabilities: Describe the organization, its qualifications and capabilities to deliver the proposed project. Describe the role and qualifications of key collaborating organizations/partners (if applicable) and how they add value to the project and demonstrate commitment to working together to implement the project. Describe the key personnel who are in place or will be recruited to implement, evaluate, and complete the project.

4.4.5. References

Provide a concise and relevant list of references cited for the application. The successful applicant will provide referenced evidence and literature support for the proposed project.

4.4.6. CPRIT Grants Summary (download template)

Provide a description of the progress or final results of **all** CPRIT-funded projects of the PD or Co-PD, regardless of their connection to this application. Indicate how the current application builds on the previous work or addresses new areas of cancer prevention and control services. Applications that are missing this document and for which CPRIT records show a PD and/or Co-PD with previous or current CPRIT funds will be administratively withdrawn.

4.4.7. Budget and Justification (complete online)

Provide a brief outline and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, travel, equipment, supplies, contractual expenses, and other expenses. CPRIT funds will be distributed on a reimbursement basis. Applications requesting more than the maximum allowed cost (total costs) as specified in <u>Section 2.5</u> will be administratively withdrawn.

- **Personnel:** The individual salary cap for CPRIT awards is \$200,000 per year. Describe the source of funding for all project personnel where CPRIT funds are not requested.
- **Travel:** PDs and related project staff are expected to attend CPRIT's conference. CPRIT funds may be used to send up to 2 people to the conference.
- Equipment: Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application. Justification must be provided for why funding for this equipment cannot be found elsewhere; CPRIT funding should not supplant existing funds. Cost sharing of equipment purchases is strongly encouraged.

Other Expenses

 Indirect Costs: It is CPRIT's policy not to allow recovery of indirect costs for prevention programs.

4.4.8. Current and Pending Support and Sources of Funding (download template)

Describe the funding source and duration of all current and pending support for the proposed project, including a capitalization table that reflects private investors, if any. Information for the initial funded project need not be included.

4.4.9. Biographical Sketches (download template)

The designated PD will be responsible for the overall performance of the funded project and must have relevant education and management experience. The PD/Co-PD(s) must provide a biographical sketch that describes his or her education and training, professional experience, awards and honors, and publications and/or involvement in programs relevant to cancer prevention and/or service delivery.

The evaluation professional biographical sketch is optional. Up to 3 additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed 2 pages.

Only biographical sketches will be accepted; do not submit resumes and/or CVs.

4.4.10. Collaborating Organizations (complete online)

List all key participating organizations that will partner with the applicant organization to provide 1 or more components essential to the success of the program (e.g., evaluation).

4.4.11. Letters of Commitment

Applicants may provide optional letters of commitment and/or memoranda of understanding from community organizations, key faculty, or any other component essential to the success of the program.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively withdrawn without review.

5. APPLICATION REVIEW

5.1. Review Process Overview

All eligible applications will be reviewed using a 2-stage peer review process: (1) evaluation of applications by peer review panels and (2) prioritization of grant applications by the Prevention Review Council. In the first stage, applications will be evaluated by an independent review panel using the criteria listed below. In the second stage, applications judged to be meritorious by review panels will be evaluated by the Prevention Review Council and recommended for funding based on comparisons with applications from all of the review panels and programmatic

priorities. Programmatic considerations may include, but are not limited to, geographic distribution, cancer type, population served, and type of program or service. The scores are only 1 factor considered during programmatic review. At the programmatic level of review, priority will be given to proposed projects that target geographic regions of the state or population subgroups that are not well represented in the current CPRIT Prevention project portfolio.

Applications approved by Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6–703.8.

Each stage of application review is conducted confidentially, and all CPRIT Peer Review Panel members, Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Peer Review Panel members and Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer Review Panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee Member, a PIC Member, a Review Panel member, or a Review Council

member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

5.2. Review Criteria

Peer review of applications will be based on primary scored criteria and secondary unscored criteria, identified below. Review panels consisting of experts in the field and advocates will evaluate and score each primary criterion and subsequently assign an overall score that reflects an overall assessment of the application. The overall evaluation score will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application and responsiveness to the RFA priorities.

5.2.1. Primary Evaluation Criteria

Impact and Innovation

- Does the proposed project demonstrate creativity, ingenuity, resourcefulness, or imagination?
- Does the applicant describe the project to be disseminated and how and why it lends itself to replication and scalability?
- Does the applicant outline the target metrics established for the CPRIT-funded project and describe the effectiveness of the intervention that is being proposed for replication/dissemination?
- Do the data (results) demonstrate success of the CPRIT-funded project and justify dissemination?
- Has the applicant convincingly demonstrated the short- and long-term impacts of the project?

Project Strategy and Feasibility

- Does the proposed project address requirements of the RFA?
- Is the overall project dissemination approach, strategy, and design clearly described and supported by established theory and practice and likely to result in successful dissemination and adoption? Are 2 or more active dissemination strategies described?
- Does the proposal clearly describe an approach and demonstrate the capacity of the applicant to develop the proposed dissemination project?
- Are the proposed objectives and activities feasible within the duration of the award?
- Are possible barriers addressed and approaches for overcoming them proposed?
- If the CPRIT-funded project is to be adapted for different populations and settings, are specific adaptations and evaluation strategies clearly outlined as a part of the project?
- Does the project identify and assist potential adopters prepare to implement the intervention and/or prepare to apply for grant funding?

Evaluation

- Are specific goals and measurable objectives for each year of the project provided?
- Are the proposed measures appropriate for the project (e.g., include short and intermediate impact of dissemination activities, knowledge or behavior change among audience likely to adopt the intervention)?
- Does the application provide a clear and appropriate plan for data collection and interpretation of results to report against goals and objectives?

Organizational Qualifications and Capabilities

- Do the organization and its collaborators/partners (if applicable) demonstrate the ability to deliver the proposed project?
- Does the described role of each collaborating organization/partner (if applicable) add value to the project and demonstrate commitment to working together to implement the project?
- Are the appropriate personnel in place or been recruited to implement, evaluate, and complete the project?

5.2.2. Secondary Evaluation Criteria

Budget

- Is the budget appropriate and reasonable for the scope of the proposed work?
- Are all costs well justified?
- Is the project a good investment of Texas public funds?

6. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. Applicants are advised to review CPRIT's administrative rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires the PD of the award to submit quarterly, annual, and final progress reports.

These reports summarize the progress made toward project goals and address plans for the upcoming year and performance during the previous year(s). In addition, quarterly fiscal reporting and reporting on selected metrics will be required per the instructions to award recipients. Continuation of funding is contingent upon the timely receipt of these reports. Failure

to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract.

7. CONTACT INFORMATION

7.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding the scope and focus of applications. Before contacting the HelpDesk, please refer to the *Instructions for Applicants* document (posted by April 30, 2015), which provides a step-by-step guide to using CARS.

Dates of operation: April 30, 2015 to July 9, 2015 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time

Wednesday, 8 AM to 4 PM central time

Tel: 866-941-7146

Email: Help@CPRITGrants.org

7.2. Program Questions

Questions regarding the CPRIT Prevention program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Prevention Program Office.

Tel: 512-305-8422

Email: <u>Help@CPRITGrants.org</u>

Website: www.cprit.state.tx.us

8. RESOURCES

- The Texas Cancer Registry: http://www.dshs.state.tx.us/tcr
- The Community Guide http://www.thecommunityguide.org/index.html
- Cancer Control P.L.A.N.E.T. http://cancercontrolplanet.cancer.gov
- Guide to Clinical Preventive Services: Recommendations of the U.S. Preventive Services
 Task Force. http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/
- Brownson, RC, Colditz GA, and Proctor, EK (Editors), Dissemination and Implementation Research in Health: Translating Science to Practice. Oxford University Press, March 2012.
- Centers for Disease Control and Prevention: The Program Sustainability Assessment
 Tool: A New Instrument for Public Health Programs
 http://www.cdc.gov/pcd/issues/2014/13 0184.htm
- Centers for Disease Control and Prevention: Using the Program Sustainability Tool to Assess and Plan for Sustainability http://www.cdc.gov/pcd/issues/2014/13 0185.htm

9. REFERENCES

- 1. http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm
- 2. Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas

 Department of State Health Services, http://www.dshs.state.tx.us/tcr/default.shtm

Third Party Observer Reports



CPRIT Peer Review Meeting Observation Report

Report #2015-09-21/22-PRE

Program Name: Prevention

Panel Name: FY16.1 Prevention Peer Review Panel - 1

Panel Date: September 21, 2015 to September 22, 2015

Report Date: September 30, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Peer Review Panel-1 peer review of applications for FY16 funding. The meeting was co-chaired by Ross Brownson and Nancy Lee and held at the Hyatt Regency in Dallas TX on September 21 through September 22, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Prevention Peer Review Panel-1 panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and co-chaired by Ross Brownson and Nancy Lee on September 21 through September 22, 2015.

The independent observer noted the following during our observation:

- Sixteen applications were discussed within the Prevention Peer Review Meeting Panel to determine
 which grants would receive CPRIT funding.
- Eleven peer review panelists, two advocate reviewers, four CPRIT staff members and five SRA
 employees were present on September 21, 2015. Eleven peer review panelists, two advocate reviewers,
 three CPRIT staff members and five SRA employees were present on September 22, 2015.
- Eight conflicts of interest were identified prior to or during the meeting. Applications for seven
 conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest either
 left the room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Prevention Review Council Meeting Observation Report

Report #2015-10-23-PREV

Program Name: Prevention

Panel Name: FY16.1 Prevention Review Council

Programmatic Review

Panel Date: October 23, 2015 Report Date: October 29, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Review Council Programmatic Review peer review of applications for FY16 funding. The meeting was chaired by Stephen Wyatt and held via teleconference on October 23, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Prevention Review Council Programmatic Review held via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Stephen Wyatt on October 23, 2015.

The independent observer noted the following during our observation:

- Sixteen applications were discussed within the Prevention Review Council Meeting to determine which
 grants would receive CPRIT funding.
- Three peer review panelists, two CPRIT staff members and one SRA employee were present for the meeting.
- One conflict of interest was identified prior to or during the meeting. Applications for one conflict was
 discussed during the peer review panel. The reviewer with the conflict of interest either left the room
 or did not participate telephonically and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Prevention Cycle 16.1 Applications (Prevention Cycle 16.1 Awards Announced at November 19, 2015, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Prevention Cycle 16.1 include Cancer Prevention Promotion and Navigation to Clinical Services, Competitive Continuation/Expansion—Evidence-Based Cancer Prevention Services, Evidence-Based Cancer Prevention Services, Evidence-Based Cancer Prevention Services - Colorectal Cancer Prevention Coalition, and Dissemination of CPRIT-Funded Cancer Prevention and Control Interventions. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted
Applica	ntions considered by the	e PIC and Oversight Co	mmittee
PP160023	Sauter, Edward	The University of Texas Health Center at Tyler	Schwartz, Randy; Cole, Kirk
PP160027	Foxhall, Lewis	The University of Texas M.D. Anderson Cancer Center	Vanderpool, Robin; Cole, Kirk
PP160042	Parra-Medinca, Deborah	The University of Texas Health Science Center at San Antonio	Vanderpool, Robin
PP160046	Cuccaro, Paula	The University of Texas Health Science Center at Houston	Vanderpool, Robin
PP160047	Savas, Lara	The University of Texas Health Science Center at Houston	Brownson, Ross
PP160048	Bolin, Jane	Texas A&M University System Health Science Center	Escabedo, Luis; Cole, Kirk
PP160051	Fernandez, Maria	Texas A&M University System	Cole, Kirk

Application ID	pplication ID Applicant		Conflict Noted								
		Health Science									
		Center									
Applications Not Recommended for PIC or Oversight Committee Consideration											
PP160026	Handal, Gilbert	Texas Tech	Escobedo, Luis								
		University Health									
		Sciences Center at El									
		Paso									
PP160043	Gonzalez, Hector	City of Laredo Health	Escobedo, Luis								
		Department									

De-Identified Overall Evaluation Scores

Dissemination of CPRIT-Funded Cancer Prevention and Control Interventions

Prevention Cycle 16.1

Application ID	Final Overall Evaluation Score
PP160048*	3.1
PP160051*	3.6

^{*=}Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

Pete Geren
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to pgcprit@sidrichardson.org

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Mr. Roberts and Mr. Geren,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for CPRIT Prevention grant awards. The applicants on the attached list of submitted proposals responded to CPRIT requests for applications (RFA) released for the first review cycle of FY2016. These recommendations reflect 50+ hours of work by individual reviewers and include panel discussion of the applicants' proposals, in addition to the PRC's programmatic review.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are provided for each grant application. The PRC did not make changes to the goals, timelines, or project objectives requested by the applicants. When the PRC did not follow the rank ordered scores in developing its recommended funding order a justification, based upon established programmatic priorities outlined in the RFAs, is provided.

The projected funding available for this fiscal year is \$27,965,885. However, the recent interpretation that annual prevention program funding is 10% of the CPRIT awarded dollars within a fiscal year could impact the dollars available. With the second funding cycle for the fiscal year underway, the PRC opted for a conservative approach to its recommendations for this cycle. Recommendations are provided at two levels: (1) initially fund 12 projects totaling an estimated \$13,247,742 and (2) depending upon the availability of funds later in the fiscal year, fund an additional 2 projects (PP160046 and PP160033 totaling \$2,999,657).

Our recommendations meet the PRC's standards for grant award funding of projects that are evidence-based, deliver programs or services to underserved populations, and focus on primary, secondary or tertiary prevention. In making these recommendations the PRC also considered the available funding, the composition of the current portfolio, and the programmatic priorities in the RFA which include potential for impact and return on investment, geographic distribution, cancer type and type of program. All of the recommended grants address one or more of the Prevention Program priorities.

Sincerely,

Stephen W. Wyatt, DMD, MPH Chair, CPRIT Prevention Review Council

App ID	Mech ·	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP16004 9	CCE- EBP	Expansion of a comprehensive cervical cancer screening program for medically underserved women in Harris County	Anderson, Matthew L	Baylor College of Medicine	\$1,500,000	1.9			1	
PP16004 7	CCE- EBP	A community based program to increase breast and cervical cancer screening and HPV vaccination to reduce the impact of breast and certical cancer among Latinas	Savas, Lara S	The University of Texas Health Science Center at Houston	\$1,387,005	2.7	Steps that will be taken to assess actual # of screenings and vaccinations for participants in educational sessions are not explained. It appears that only women completing the surveys will be followed. Evaluation of outcomes for all participants is not provided, only provided for women completing surveys. Budget is unclear about number of screenings that will be paid for; number of financially supported	Changes not recommended-PRC reviewed peer review comments and determined those comments did NOT impact decision to recommend or impact rank order	2	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							screening isn't clearly stated.			
PP16004 2	EBP	Using Best Practices to Promote HPV vaccination in Rural Primary Care Settings	Parra- Medina, Deborah	The University of Texas Health Science Center at San Antonio	\$1,295,493	2.8	Outcomes evaluation doesn't have baseline and % increase noted. A highly intensive program is being implemented and the high cost is a barrier. If the cost is reduced, the applicability of the proposed approach may be enhanced. Reviewers would like the applicants to clarify why the increase in the budget from the previous grant to this grant. Why has the per person	changes not recommended- PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	3	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							cost increased so much?			
PP16003 2	PN	Family Health History-based Colorectal Cancer Prevention and Navigation to Clinical Services among Uninsured Chinese Americans in Texas	Chen, Lei- Shih	Texas A&M University	\$399,993	3.0	Findings from this study should be applied to follow-up treatment for the participants. Plans for this are lacking and should be provided.	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	4	
PP16005 6	PN	REACH Rural Education and Awareness for Community Health	Hoelscher, Bill	Coastal Bend Wellness Foundatio n	\$379,698	3.0	Should be clarified that \$25 gift card is not being offered to change the behavior of the participants.	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	5	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP16001 0	EBP	Maximizing opportunities for HPV vaccination in the Golden Triangle	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	\$1,409,909	3.1	Ask applicants why they do not plan to vaccinate young adults on college campuses. In addition, students could be used to help with recruitment	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	6	
PP16004 8	DI	Training CHWs for More Effective Cancer Education and Navigation	Bolin, Jane N	Texas A&M University System Health Science Center	\$300,000	3.1			7	
PP16002 3	EBP- CRC	Optimizing Colorectal Cancer Screening in East Texas	Sauter, Edward	The University of Texas Health Center at Tyler	\$2,299,753	3.3	Recommendation was made in previous application that providing FIT isn't evidence-based for people who are at significant risk for CRC; this isn't consistent with ACS guidelines. Ask how they came up with \$275/colonoscopy	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	8	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP16003 6	CCE- EBP	Establishing a Comprehensiv e Cancer Prevention and Support Program within Asian American Communities in Houston and Austin Areas of Texas	Sun, Helen	Light and Salt Associatio n	\$1,101,986	3.3	Request that the applicant provides a leadership plan that includes input from the three communities being targeted: Vietnames, Korean, and Filipino	changes not recommended-PRC reveiwed peer review comments and determined they did not impact decision to recommend or impact rank order	9	
PP16002 7	EBP	Improving Service Delivery to Cancer Survivors in Primary Care Settings	Foxhall, Lewis E	The University of Texas M. D. Anderson Cancer Center	\$1,374,127	3.5	Not clear how project will add to what is already happening in clinic. This is a large, complex project and not clear how it will be managed on a daily basis. Budget is weak and justification for some of the positions is lacking	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	10	Recommende d out of score order above one with higher score due to ROI and cancer type
PP16005 1	DI	Dissemination of an Evidence- Based HPV Vaccination Intervention in Community and Clinical Settings	Fernandez , Maria E	The University of Texas Health Science Center at Houston	\$299,778	3.6	List of current awards doesn't specify PD participation; it should be verified that PD isn't overcommitted. Budget seems somewhat personnel heavy and accounts for a	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	11	Recommende d out of score order above one with higher score due to type of program

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							large majority of voerall costs; careful review of personnel and their exact roles and responsibilities and whether or not any of the services are duplicative may be warranted.			
PP16001 1	CCE- EBP	GRACIAS Texas: Genetic Risk Assessment for Cancer in All South Texas	Tomlinson , Gail E	The University of Texas Health Science Center at San Antonio	\$1,500,000	2.7			12	Recommende d but ranked out of score order due to 1) ROI may be limited; large numbers need to be screened to identify at risk pop.
PP16004 6	EBP	Using social marketing and mobile school-based vaccination clinics to increase HPV vaccination uptake in highrisk geographic areas	Cuccaro, Paula	The University of Texas Health Science Center at Houston	\$1,499,668	2.2			13	Recommende d but out of score order due to 1) geography- several HPV grants in Harris county, 2) ROI-costs for education vs services

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP16003	CCE- EBP	Increasing cancer control behaviors among the underserved: A collaboration with Texas 2-1-1 programs	Fernandez , Maria E	The University of Texas Health Science Center at Houston	\$1,499,989	2.4			14	Recommende d but out of score order due to 1) geography- several HPV grants in Harris county, 2) cancer type- availabilty of breast and cervical services 3) ROI-costs for education vs services
				Initial funding (Rank #1- 12)	\$13,247,74 2					
				(Rank #13+14)	\$2,999,657					
				2nd funding	\$16,247,39 9					



CEO Affidavit Supporting Information

FY 2016—Cycle 1
Evidence-Based Cancer Prevention Services

Request for Applications



REQUEST FOR APPLICATIONS RFA P-16-EBP-1

Evidence-Based Cancer Prevention Services

Please also refer to the "Instructions for Applicants" document, which will be posted April 30, 2015

Application Receipt Opening Date: April 30, 2015

Application Receipt Closing Date: July 9, 2015

FY 2016

Fiscal Year Award Period

September 1, 2015-August 31, 2016

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RFA VERSION HISTORY

Rev 4/16/15 RFA release

1. ABOUT CPRIT

The state of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the state of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Prevention Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The Prevention Program's principles and priorities will also guide CPRIT staff and the Prevention Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

Established Principles:

- Fund evidence-based interventions and their dissemination
- Support the prevention continuum of primary, secondary and tertiary (includes survivorship) prevention interventions

Prevention Program Priorities

- Prioritize populations and areas of greatest need, greatest potential for impact
- Focus on underserved populations
- Increase targeting of preventive efforts to areas where significant disparities in cancer incidence or mortality in the state exist

2. FUNDING OPPORTUNITY DESCRIPTION

2.1. Summary

The ultimate goals of the CPRIT Prevention Program are to reduce overall cancer incidence and mortality and to improve the lives of individuals who have survived or are living with cancer. The ability to reduce cancer death rates depends in part on the application of currently available evidence-based technologies and strategies. CPRIT will foster the primary, secondary, and tertiary prevention of cancer in Texas by providing financial support for a wide variety of evidence-based risk reduction, early detection, and survivorship interventions.

The **Evidence-Based Cancer Prevention Services (EBP)** award mechanism seeks to fund programs that greatly challenge the status quo in cancer prevention and control services. The proposed program should be designed to reach and serve as many people as possible. Partnerships with other organizations that can support and leverage resources are strongly encouraged. A coordinated submission of a collaborative partnership program in which all partners have a substantial role in the proposed project is preferred.

2.2. Project Objectives

CPRIT seeks to fund projects that will do the following:

- Address multiple components of the cancer prevention and control continuum (e.g., provision of screening and navigation services in conjunction with outreach and education of the priority population as well as health care provider education);
- Offer effective and efficient systems of delivery of prevention services based on the
 existing body of knowledge about and evidence for cancer prevention in ways that far
 exceed current performance in a given service area;
- Offer systems and/or policy changes that are sustainable over time;
- Provide tailored, culturally appropriate outreach and accurate information on early
 detection and prevention to the public and health care professionals that results in a health
 impact that can be measured;
- Deliver evidence-based survivorship services aimed at reducing the morbidity associated with cancer diagnosis and treatment.

2.3. Award Description

The Evidence-Based Cancer Prevention Services RFA solicits applications for projects up to 36 months in duration that will deliver evidence-based services in at least 1 of the following cancer prevention and control areas. For this cycle, CPRIT is accepting new applications **limited to the following:**

- Delivery of vaccines that reduce the risk of cancer
- Tobacco cessation interventions
- Screening and early detection services (see Areas of Emphasis)
- Survivorship services

In addition to other primary prevention and screening/early detection services, CPRIT considers counseling services (e.g., tobacco cessation, survivorship, exercise, and nutrition) when done on a one-on-one basis or in small groups as clinical services.

This mechanism will fund case management/patient navigation if it is paired with the delivery of a clinical service (e.g., human papillomavirus [HPV] vaccination/screening). Applicants offering screening services must ensure that there is access to treatment services for patients with cancers that are detected as a result of the program and must describe access to treatment services in their application. In the case of screening for hepatitis C, applicants must provide navigation to ensure access to viral treatments and must describe the process for ensuring access to treatment services.

CPRIT's services grants are intended to fund prevention interventions that have a demonstrated evidence base and are culturally appropriate for the priority population.

CPRIT recognizes that evidence-based services have been developed but not implemented or tested in all populations or service settings. In such cases, other forms of evidence (eg, preliminary evaluation or pilot project data) that the proposed service is appropriate for the population and has a high likelihood of success must be provided. The applicant must fully describe the base of evidence and any plans to adapt and evaluate the implementation of the program for the specific audience or situation.

Comprehensive projects are required. Comprehensive projects include a continuum of services and systems and/or policy changes and comprise all or some of the following: Public

and/or professional education and training, patient support of behavior modification, outreach, delivery of clinical services, and followup navigation.

This RFA encourages traditional and nontraditional partnerships as well as leveraging of existing resources and dollars from other sources. The applicant should coordinate and describe a collaborative partnership program in which all partners have a substantial role in the proposed project. Letters of commitment describing their role in the partnership are required from all partners.

CPRIT expects measurable outcomes of supported activities, such as a significant increase over baseline (for the proposed service area) in the provision of evidence-based services, changes in provider practice, systems changes, and cost-effectiveness. Applicants must demonstrate how these outcomes will ultimately impact incidence, mortality, morbidity, or quality of life.

Under this RFA, CPRIT will not consider the following:

- Projects focusing solely on systems and/or policy change or solely on education and/or outreach that do not include the delivery of services
- Projects focusing solely on case management/patient navigation services. Case
 management/patient navigation services must be paired with the delivery of a clinical
 service. Furthermore, while navigation to the point of treatment of cancer is required
 when cancer is discovered through a CPRIT-funded project, applications seeking funds to
 provide coordination of care while an individual is in treatment are not allowed under this
 RFA.
- Projects for continuation/expansion of a currently or previously funded project.
 Applications for continuation/expansion should be submitted in response to the Competitive Continuation/Expansion RFA.
- Projects requesting CPRIT funding for Quitline services. Applicants proposing the
 utilization of Quitline services should communicate with the Tobacco Prevention and
 Control program prior to submitting a CPRIT grant application to discuss the services
 currently offered by the Texas Department of State Health Services (DSHS).
- Projects focusing on computerized tomography (CT) screening for lung cancer

- **Projects involving prevention/intervention research.** Applicants interested in prevention research should review CPRIT's research RFAs (available at http://www.cprit.state.tx.us).
- Resources for the treatment of cancer or viral treatment for hepatitis.

2.3.1. Priorities

Types of Cancer: Applications addressing any cancer type(s) that are responsive to this RFA will be considered for funding.

Priority Populations: The age of the priority population and frequency of screening plans for provision of clinical services described in the application must comply with established and current national guidelines (e.g., US Preventive Services Task Force [USPSTF], American Cancer Society).

Priority populations are subgroups that are disproportionately affected by cancer. CPRIT-funded efforts must address 1 or more of these priority populations:

- Underinsured and uninsured individuals
- Geographically or culturally isolated populations
- Medically unserved or underserved populations
- Populations with low health literacy skills
- Geographic regions or populations of the state with higher prevalence of cancer risk factors (e.g., obesity, tobacco use, alcohol misuse, unhealthy eating, sedentary lifestyle)
- Racial, ethnic, and cultural minority populations
- Other populations with low screening rates, high incidence rates, and high mortality rates, focusing on individuals never before screened or who are significantly out of compliance with nationally recommended screening guidelines.

Geographic and Population Priority: For applications submitted in response to this announcement, at the programmatic level of review conducted by Prevention Review Council (see Section 5.1), priority will be given to projects that target geographic regions of the state and population subgroups that are not adequately covered by the current CPRIT Prevention project portfolio (see http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-andcontrol/ and http://www.cprit.state.tx.us/funded-grants/)

2.3.2. Specific Areas of Emphasis

Applications addressing any type of education and outreach programs that include navigation to services and that are responsive to this RFA will be considered. However, CPRIT has identified the following areas of emphasis for this cycle of awards.

CPRIT is interested in applications focused on the following:

A. Primary Prevention

Priority will be given to projects that, through evidence-based efforts, address and can positively influence local policy or systems change that can lead to sustainable change in desired health behaviors.

Tobacco Prevention and Control

- Decreasing tobacco use in areas of the state that have higher smoking rates per capita than other areas of the state.
 - Health Service Regions (HSRs) 2, 4, and 5 have significantly higher tobacco use among adults than in other regions of the state. For more information about maps of HSRs, please visit http://www.dshs.state.tx.us/regions/state.shtm.

HPV Vaccination

- Increasing access to, delivery of, and completion of the HPV vaccine regimen to males and females through evidence-based intervention efforts.
 - HPV vaccine completion rates are low (15% for males and 39% for females)
 across the state compared to the CDC goals of 75% completion rates.¹

Liver Cancer

- Decreasing disparities in incidence and mortality rates for hepatocellular cancer (HCC)
 by increasing the provision of vaccination and screening for hepatitis B virus and
 screening for hepatitis C virus (following USPSTF guidelines), diagnostic testing,
 navigation that ensures access to viral treatment, and education on risk factors and on
 reducing transmission of hepatitis.
 - HCC incidence is significantly higher in Texas Hispanics, blacks, and Asian/Pacific Islanders than in non-Hispanic whites.²

- Significantly higher HCC rates in Texas Hispanics versus the United States are driven by very high rates among Hispanics in South Texas.
- o Males have significantly higher incidence and mortality rates than females.²
- Age at diagnosis is shifting toward younger patients, both in Texas and the United States ²

B. Secondary Prevention - Screening and Early Detection Services

Applicants should select preventive services using current evidence-based national clinical guidelines (e.g., USPSTF, American Cancer Society).

Colorectal Cancer

- Increasing screening/detection rates in HSR 1 through 6 and HSR 9.
 - The highest rates of cancer incidence and mortality are found in these regions of Texas.²
- Decreasing disparities in incidence and mortality rates of colorectal cancer for racial/ethnic populations and rural communities.
 - African Americans have the highest incidence and mortality rates, followed by non-Hispanic whites and Hispanics.²
- Decreasing incidence and mortality rates in rural counties.
 - Incidence and mortality rates are higher in rural counties compared to urban counties.²

Cervical Cancer

- Increasing screening/detection rates for women in Texas-Mexico border counties.
 - Women in these counties have a 30% higher cervical cancer mortality rate than women in nonborder counties².
- Decreasing disparities in racial/ethnic populations.
 - Hispanics have the highest incidence rates, while African Americans have the highest mortality rates.²
- Reaching women never before screened or who have not been screened

Breast Cancer

• Increasing screening/detection rates in rural and medically underserved areas of the state

• Reaching women never before screened

Data on cancer incidence and mortality is provided by the Texas Cancer Registry.² For more information about cancer in Texas, visit CPRIT's website at http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control or visit the Texas Cancer Registry site at http://www.dshs.state.tx.us/tcr/.

C. Tertiary Prevention - Survivorship Services

Priority for funding will be given to survivorship projects that demonstrate a likelihood of success based on available evidence and that can demonstrate and measure an improvement in quality of life in 1 of more of the following areas:

- Preventing secondary cancers and recurrence of cancer
- Managing the after effects of cancer and treatment to maximize quality of life and number of years of healthy life
- Minimizing preventable pain, disability, and psychosocial distress

Applicants proposing survivorship projects may address people with any type of cancer.

2.3.3. Outcome Metrics

The applicant is required to describe final outcome measures for the project. Interim measures that are associated with the final outcome measures should be identified and will serve as a measure of program effectiveness and public health impact. Applicants are required to clearly describe their assessment and evaluation methodology. **Baseline data for each measure proposed are required**. In addition, applicants should describe how funds from the CPRIT grant will improve outcomes over baseline. If the applicant is not providing baseline data for a measure, the applicant must provide a well-justified explanation and describe clear plans and method(s) of measurement to collect the data necessary to establish a baseline.

Reporting Requirements

Funded projects are required to report quantitative output and outcome metrics (as appropriate for each project) through the submission of quarterly progress reports, annual reports, and a final report.

- Quarterly progress report sections include, but are not limited to:
 - Narrative on project progress (required)
 - People reached activities
 - o Services, other than clinical services, provided to the public/professionals
 - Actions taken by people/professionals as a result of education or training, including percentage of people reporting sustained behavior change
 - Clinical services provided
 - Abnormal results and precursors or cancers detected
- Annual and Final progress report sections include, but are not limited to the following:
 - Key accomplishments, including qualitative analysis of policy change and/or lasting systems change
 - Progress against goals and objectives, including percentage increase over baseline in provision of age- and risk-appropriate comprehensive preventive services to eligible men and women in a defined service area; for example:
 - Percentage increase over baseline in number of people served
 - Percentage increase over baseline in number of services provided
 - Completion of all required doses of vaccine
 - Number of people quitting tobacco use and sustaining healthy behavior
 - Percentage increase over baseline in cancers detected
 - Percentage increase in early-stage cancer diagnoses in a defined service area
 - Materials produced and publications
 - Economic impact of the project

2.4. Eligibility

- The applicant must be a Texas-based entity, such as a community-based organization, health institution, government organization, public or private company, college or university, or academic health institution.
- The designated Program Director (PD) will be responsible for the overall performance of the funded project. The PD must have relevant education and management experience and must reside in Texas during the project performance time.

- The evaluation of the project must be headed by a professional who has demonstrated expertise in the field (e.g., qualitative or quantitative statistics) and who resides in Texas during the time that the project is conducted.
- The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PD, any
 senior member or key personnel listed on the grant application, or any officer or director
 of the grant applicant's organization or institution is related to a CPRIT Oversight
 Committee member.
- The applicant may submit more than 1 application, but each application must be for
 distinctly different services without overlap in the services provided. Applicants who do
 not meet this criterion will have all applications administratively withdrawn without peer
 review.
- If the applicant or a partner is an existing DSHS contractor, CPRIT funds may not be
 used as a match, and the application must explain how this grant complements or
 leverages existing state and federal funds. DSHS contractors who also receive CPRIT
 funds must be in compliance with and fulfill all contractual obligations within CPRIT.
 CPRIT and DSHS reserve the right to discuss the contractual standing of any contractor
 receiving funds from both entities.
- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Subcontracting and collaborating organizations may include public, notfor-profit, and for-profit entities. Such entities may be located outside of the state of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant organization is eligible to receive a grant award only if the applicant
 certifies that the applicant organization, including the PD, any senior member or key
 personnel listed on the grant application, or any officer or director of the grant applicant's
 organization (or any person related to 1 or more of these individuals within the second
 degree of consanguinity or affinity), has not made and will not make a contribution to
 CPRIT or to any foundation created to benefit CPRIT.

- The applicant must report whether the applicant organization, the PD, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, (whether slated to receive salary or compensation under the grant award or not), are currently ineligible to receive federal grant funds because of scientific misconduct or fraud or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. CPRIT grants are funded on a reimbursement-only basis. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in Section 6. All statutory provisions and relevant administrative rules can be found at http://www.cprit.state.tx.us.

2.4.1. Resubmission Policy

More than **1 resubmission** is not permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PD for a project or a change of title for a project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission.

2.5. Funding Information

Applicants may request any amount of funding up to a maximum of \$1.5 million in total funding over a maximum of 36 months. Grant funds may be used to pay for clinical services, navigation services, salary and benefits, project supplies, equipment, costs for outreach and education of populations, and travel of project personnel to project site(s). Requests for funds to support construction, renovation, or any other infrastructure needs or requests to support lobbying will not be approved under this mechanism. Grantees may request funds for travel for 2 project staff to attend CPRIT's conference.

The budget should be proportional to the number of individuals receiving programs and services, and a significant proportion of funds is expected to be used for program delivery as opposed to program development. In addition, CPRIT seeks to fill gaps in funding rather than replace existing funding, supplant funds that would normally be expended by the applicant's organization, or make up for funding reductions from other sources.

3. KEY DATES

RFA

RFA release April 16, 2015

Application

Online application opens April 30, 2015, 7 AM central time

Application due July 9, 2015, 3 PM central time

Application review September 2015

Award

Award notification November 2015
Anticipated start date December 2015

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

4. APPLICATION SUBMISSION GUIDELINES

4.1. Instructions for Applicants document

It is imperative that applicants read the accompanying instructions document for this RFA (https://CPRITGrants.org). Requirements may have changed from previous versions.

4.2. Online Application Receipt System

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be considered eligible for evaluation. The PD must create a user account in the system to start and submit an application. The Co-PD, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (a person authorized to sign and

submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on April 30, 2015, and must be submitted by 3 PM central time on July 9, 2015. Detailed instructions for submitting an application are in the *Instructions for Applicants* document, posted on CARS.

Submission of an application is considered an acceptance of the terms and conditions of the

4.2.1. Submission Deadline Extension

RFA.

The submission deadline may be extended for 1 or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via email to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

4.3. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Refer to the *Instructions for Applicants* document for details. Submissions that are missing 1 or more components or do not meet the eligibility requirements will be administratively withdrawn without review.

4.3.1. Abstract and Significance (5,000 characters)

Clearly explain the problem(s) to be addressed, the approach(es) to the solution, and how the application is responsive to this RFA. In the event that the project is funded, the abstract will be made public; therefore no proprietary information should be included in this statement. Initial compliance decisions are based in part upon review of this statement.

The required abstract format is as follows (use headings as outlined below):

- Need: Include a description of need in the specific service area. Include rates of
 incidence, mortality, and screening in the service area compared to overall Texas rates.
 Describe barriers, plans to overcome these barriers, and the priority population to be
 served.
- Overall Project Strategy: Describe the project and how it will address the identified need. Clearly explain what the project is and what it will specifically do, including the

- services to be provided and the process/system for delivery of services and outreach to the priority population.
- **Specific Goals:** State specifically the overall goals of the proposed project; include the estimated overall numbers of people (public and/or professionals) reached and people (public and/or professionals) served.
- **Innovation:** Describe the creative components of the proposed project and how it differs from current programs or services being provided.
- **Significance and Impact:** Explain how the proposed project, if successful, will have a unique and major impact on cancer prevention and control for the population proposed to be served and for the state of Texas.

4.3.2. Goals and Objectives

List specific goals and **measurable** objectives for each year of the project. A baseline and method(s) of measurement are required for each objective. Provide both raw numbers and percent changes for the baseline and target. Applicants must explain plans to establish baseline and describe method(s) of measurement in cases where a baseline has not been defined.

4.3.3. Project Timeline

Provide a project timeline for project activities that includes deliverables and dates. Use Years 1, 2, 3 and months 1,2,3, etc., as applicable instead of specific months or years (e.g., Year 1, Months 3-5, not 2017, March – May).

4.3.4. Project Plan (15 pages maximum; fewer pages permissible)

The required project plan format follows. Applicants must use the headings outlined below. Applications not following the required format will be administratively withdrawn.

Background: Briefly present the rationale behind the proposed service, emphasizing the critical barriers to current service delivery that will be addressed. Identify the evidence-based service to be implemented for the priority population. If evidence-based strategies have not been implemented or tested for the specific population or service setting proposed, provide evidence that the proposed service is appropriate for the population and has a high likelihood of success. Baseline data for the priority population and target service area are required where applicable.

Reviewers will be aware of national and state statistics, and these should be used only to compare rates for the proposed service area. Describe the geographic region of the state that the project will serve; maps are appreciated.

Goals and Objectives (optional): Goals and Objectives will be entered in separate fields in CARS and need not be provided in the project plan. However, if desired, goals and objectives may be fully repeated or briefly summarized here.

Components of the Project: Clearly describe the need, delivery method, and evidence base (provide references) for the services as well as anticipated results. Be explicit about the base of evidence and any necessary adaptations for the proposed project. Describe why this project is nonduplicative, creative, or unique. Clearly demonstrate the ability to provide the proposed service, describe how results will be improved over baseline and the ability to reach the priority population. Applicants must also clearly describe plans to ensure access to treatment services should cancer be detected.

Evaluation Strategy: A strong commitment to evaluation of the project is required. Describe the impact on ultimate outcome measures and interim outcome measures as outlined in Section 2.3.3. Describe the plan for outcome measurements, including data collection and management methods, statistical analyses, and anticipated results. Evaluation and reporting of outcomes must be headed by a professional who has demonstrated expertise in the field of program evaluation, intervention science, cancer screening, and/or behavioral risk reduction. If needed, applicants may want to consider seeking expertise at Texas-based academic cancer centers, schools/programs of public health, prevention research centers, or the like. Applicants should budget accordingly for the evaluation activity and should involve that professional during grant application preparation to ensure, among other things, that the evaluation plan is linked to the proposed goals and objectives.

Organizational Qualifications and Capabilities: Describe the organization and its track record and success in providing programs and services. Describe the role and qualifications of the key collaborators/partners in the project. Include information on the organization's financial stability and viability. To ensure access to preventive services and reporting of services outcomes, applicants should demonstrate that they have provider partnerships and agreements (via memoranda of understanding) or commitments (via letters of commitment) in place.

Integration and Capacity Building: CPRIT funds projects that target the unmet needs not sufficiently covered by other funding sources, and full maintenance of the project may not be feasible. This is especially the case when the project involves the delivery of clinical services. Educational and other less costly interventions may be more readily sustained. Full maintenance of a project, the ability of the grantee's setting or community to continue to deliver the health benefits of the intervention as funded, is not required; however, efforts toward maintenance should be described.

It is expected that steps toward integration and capacity building for components of the project will be taken and plans for such be fully described in the application. *Integration* is defined as the extent the evidence-based intervention is integrated within the culture of the grantee's setting or community through policies and practice. *Capacity building* is any activity (e.g., training, identification of alternative resources, building internal assets) that builds durable resources and enables the grantee's setting or community to continue the delivery of <u>some or all</u> components of the evidence-based intervention

Elements of integration and capacity building may include, but are not limited to, the following:

- Developing ownership, administrative networks, and formal engagements with stakeholders
- Developing processes for each practice/location to incorporate services into its structure beyond project funding
- Identifying and training of diverse resources (human, financial, material, and technological)
- Implementing policies to improve effectiveness and efficiency (including costeffectiveness) of systems

Dissemination and Scalability (Expansion): Describe how the project lends itself to dissemination to or application by other communities and/or organizations in the state or expansion in the same communities. Describe plans for dissemination of positive and negative project results and outcomes. Dissemination of project results and outcomes, including barriers encountered and successes achieved, is critical to building the evidence base for cancer prevention and control efforts in the state. Dissemination methods may include, but are not limited to, presentations, publications, abstract submissions, and professional journal articles, etc.

4.3.5. People Reached (complete online)

Provide the estimated overall number of people (members of the public and professionals) to be reached by the funded project. The applicant is required to itemize separately the types of noninteractive education and outreach activities, with estimates, that led to the calculation of the overall estimates provided. Refer to the <u>Appendix</u> for definitions.

4.3.6. People Served (complete online)

Provide the estimated overall number of people (members of the public and professionals) to be served by the funded project. The applicant is required to itemize separately the education, navigation, and clinical activities/services, with estimates, that led to the calculation of the overall estimates provided. Refer to the Appendix for definitions.

4.3.7. References

Provide a concise and relevant list of references cited for the application. The successful applicant will provide referenced evidence and literature support for the proposed services.

4.3.8. Resubmission Summary (if applicable; download template)

Describe the approach to the resubmission and how reviewers' comments were addressed. The summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission; the applicant is not responsible for providing this document.

4.3.9. CPRIT Grants Summary (download template)

Provide a description of the progress or final results of **all** CPRIT-funded projects of the PD or Co-PD, regardless of their connection to this application. Indicate how the current application builds on the previous work or addresses new areas of cancer prevention and control services. Applications that are missing this document and for which CPRIT records show a PD and/or Co-PD with previous or current CPRIT funds will be administratively withdrawn.

4.3.10. Budget and Justification (complete online)

Provide a brief outline and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, travel, equipment, supplies, contractual expenses,

services delivery, and other expenses. CPRIT funds will be distributed on a reimbursement basis. Applications requesting more than the maximum allowed cost (total costs) as specified in Section 2.5 will be administratively withdrawn.

- Cost Per Person Served: The cost per person served will be automatically calculated
 from the total cost of the project divided by the total number of people (both public and
 professionals) served (refer to <u>Appendix</u>). A significant proportion of funds is expected to
 be used for program delivery as opposed to program development and organizational
 infrastructure.
- **Personnel:** The individual salary cap for CPRIT awards is \$200,000 per year. Describe the source of funding for all project personnel where CPRIT funds are not requested.
- **Travel:** PDs and related project staff are expected to attend CPRIT's conference. CPRIT funds may be used to send up to 2 people to the conference.
- Equipment: Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application. Justification must be provided for why funding for this equipment cannot be found elsewhere; CPRIT funding should not supplant existing funds. Cost sharing of equipment purchases is strongly encouraged.
- **Services Costs:** CPRIT reimburses for services using Medicare reimbursement rates. Describe the source of funding for all services where CPRIT funds are not requested.

• Other Expenses:

- o **Incentives:** Use of incentives or positive rewards to change or elicit behavior is allowed; however, incentives may only be used based on strong evidence of their effectiveness for the purpose and in the priority population identified by the applicant. CPRIT will not fund cash incentives. The maximum dollar value allowed for an incentive per person, per activity or session, is \$25.
- Indirect Costs: It is CPRIT's policy not to allow recovery of indirect costs for prevention programs.
- Costs Not Related to Cancer Prevention and Control: CPRIT does not allow recovery of any costs for services not related to cancer (e.g., health physicals, HIV testing).

4.3.11. Current and Pending Support and Sources of Funding (download template)

Describe the funding source and duration of all current and pending support for the proposed project, including a capitalization table that reflects private investors, if any. Information for the initial funded project need not be included.

4.3.12. Biographical Sketches (download template)

The designated PD will be responsible for the overall performance of the funded project and must have relevant education and management experience. The PD/Co-PD(s) must provide a biographical sketch that describes his or her education and training, professional experience, awards and honors, and publications and/or involvement in programs relevant to cancer prevention and/or service delivery.

The evaluation professional must provide a biographical sketch.

Up to 3 additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed 2 pages.

Only biographical sketches will be accepted; do not submit resumes and/or CVs.

4.3.13. Collaborating Organizations (complete online)

List all key participating organizations that will partner with the applicant organization to provide 1 or more components essential to the success of the program (e.g., evaluation, clinical services, recruitment to screening, etc.).

4.3.14. Letters of Commitment

Applicants should provide letters of commitment and/or memoranda of understanding from community organizations, key faculty, or any other component essential to the success of the program.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively withdrawn without review.

5. APPLICATION REVIEW

5.1. Review Process Overview

All eligible applications will be reviewed using a 2-stage peer review process: (1) evaluation of applications by peer review panels and (2) prioritization of grant applications by the Prevention Review Council. In the first stage, applications will be evaluated by an independent review panel using the criteria listed below. In the second stage, applications judged to be meritorious by review panels will be evaluated by the Prevention Review Council and recommended for funding based on comparisons with applications from all of the review panels and programmatic priorities. Programmatic considerations may include, but are not limited to, geographic distribution, cancer type, population served, and type of program or service. The scores are only 1 factor considered during programmatic review. At the programmatic level of review, priority will be given to proposed projects that target geographic regions of the state or population subgroups that are not well represented in the current CPRIT Prevention project portfolio.

Applications approved by Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

Each stage of application review is conducted confidentially, and all CPRIT Peer Review Panel members, Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Peer Review Panel members and Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer Review Panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee Member, a PIC Member, a Review Panel member, or a Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

5.2. Review Criteria

Peer review of applications will be based on primary scored criteria and secondary unscored criteria, identified below. Review panels consisting of experts in the field and advocates will evaluate and score each primary criterion and subsequently assign an overall score that reflects an overall assessment of the application. The overall evaluation score will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application and responsiveness to the RFA priorities.

5.2.1. Primary Evaluation Criteria

Impact and Innovation

- Do the proposed services address an important problem or need in cancer prevention and control? Do the proposed project strategies support desired outcomes in cancer incidence, morbidity, and/or mortality? Does the proposed project demonstrate creativity, ingenuity, resourcefulness, or imagination? Does it take evidence-based interventions and apply them in innovative ways to explore new partnerships, new audiences, or improvements to systems?
- Does the program address adaptation, if applicable, of the evidence-based intervention to the priority population? Is the base of evidence clearly explained and referenced?
- Does the program address known gaps in prevention services and avoid duplication of effort?
- If applicable, have collaborative partners demonstrated that the collaborative effort will provide a greater impact on cancer prevention and control than the applicant organization's effort separately?
- Will the project reach and serve an appropriate number of people based on the budget allocated to providing services and the cost of providing services?

Project Strategy and Feasibility

- Does the proposed project provide services specified in the RFA?
- Are the overall program approach, strategy, and design clearly described and supported
 by established theory and practice? Are the proposed objectives and activities feasible
 within the duration of the award? Has the applicant convincingly demonstrated the shortand long-term impacts of the project?
- Are possible barriers addressed and approaches for overcoming them proposed?
- Are the priority population and culturally appropriate methods to reach the priority population clearly described?
- If applicable, does the application demonstrate the availability of resources and expertise to provide case management, including followup for abnormal results and access to treatment?

• Does the program leverage partners and resources to maximize the reach of the services proposed? Does the program leverage and complement other state, federal, and nonprofit grants?

Outcomes Evaluation

- Are specific goals and measurable objectives for each year of the project provided?
- Are the proposed outcome measures appropriate for the services provided, and are the expected changes clinically significant?
- Does the application provide a clear and appropriate plan for data collection and management, statistical analyses, and interpretation of results to follow, measure, and report on the project's outcomes?
- Are clear baseline data provided for the priority population, or are clear plans included to collect baseline data?
- If an evidence-based intervention is being adapted in a population where it has not been implemented or tested, are plans for evaluation of barriers, effectiveness, and fidelity to the model described?
- Is the qualitative analysis of planned policy or system changes described?

Organizational Qualifications and Capabilities

- Do the organization and its collaborators/partners demonstrate the ability to provide the proposed preventive services? Does the described role of each collaborating organization make it clear that each organization adds value to the project and is committed to working together to implement the project?
- Have the appropriate personnel been recruited to implement, evaluate, and complete the project?
- Is the organization structurally and financially stable and viable?

Integration and Capacity Building

- Does the applicant describe steps that will be taken and components of the project that will be integrated into the organization through policies and practices?
- Does the applicant describe steps that will be taken or components of the project that will remain (e.g., trained personnel, identification of alternative resources, building internal

assets) to continue the delivery of <u>some or all</u> components of the evidence-based intervention once CPRIT funding ends.

5.2.2. Secondary Evaluation Criteria

Budget

- Is the budget appropriate and reasonable for the scope and services of the proposed work?
- Is the cost per person served appropriate and reasonable?
- Is the proportion of the funds allocated for direct services reasonable?
- Is the project a good investment of Texas public funds?

Dissemination and Scalability

- Are plans for dissemination of the project's results and outcomes, including barriers encountered and successes achieved, clearly described?
- Does the project or do some components of the project lend themselves to scalability/expansion by others in the state? If so, does the application describe a plan for doing so?

6. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. Applicants are advised to review CPRIT's administrative rules related to

contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires the PD of the award to submit quarterly, annual, and final progress reports. These reports summarize the progress made toward project goals and address plans for the upcoming year and performance during the previous year(s). In addition, quarterly fiscal reporting and reporting on selected metrics will be required per the instructions to award recipients. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract.

7. CONTACT INFORMATION

7.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding the scope and focus of applications. Before contacting the HelpDesk, please refer to the *Instructions for Applicants* document (posted by April 30, 2015), which provides a step-by-step guide to using CARS.

Dates of operation: April 30, 2015, to July 9, 2015 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time

Wednesday, 8 AM to 4 PM central time

Tel: 866-941-7146

Email: Help@CPRITGrants.org

7.2. Program Questions

Questions regarding the CPRIT Prevention program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Prevention Program Office.

Tel: 512-305-8422

Email: Help@CPRITGrants.org

Website: <u>www.cprit.state.tx.us</u>

8. RESOURCES

- The Texas Cancer Registry: http://www.dshs.state.tx.us/tcr
- The Community Guide http://www.thecommunityguide.org/index.html
- Cancer Control P.L.A.N.E.T. http://cancercontrolplanet.cancer.gov
- Guide to Clinical Preventive Services: Recommendations of the U.S. Preventive Services
 Task Force. http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/
- Brownson, RC, Colditz GA, and Proctor, EK (Editors), Dissemination and Implementation Research in Health: Translating Science to Practice. Oxford University Press, March 2012.
- Centers for Disease Control and Prevention: The Program Sustainability Assessment
 Tool: A New Instrument for Public Health Programs
 http://www.cdc.gov/pcd/issues/2014/13 0184.htm
- Centers for Disease Control and Prevention: Using the Program Sustainability Tool to
 Assess and Plan for Sustainability http://www.cdc.gov/pcd/issues/2014/13 0185.htm

9. REFERENCES

- 1. http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm
- 2. Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas Department of State Health Services, http://www.dshs.state.tx.us/tcr/default.shtm

10. APPENDIX: KEY TERMS

- Activities: A listing of the "who, what, when, where, and how" for each objective that will be accomplished.
- Capacity Building: Any activity (e.g., training, identification of alternative resources, building internal assets) that builds durable resources and enables the grantee's setting or community to continue the delivery of some or all components of the evidence-based intervention.
- Clinical Services: Number of clinical services such as screenings, diagnostic tests, vaccinations, counseling sessions, or other evidence-based preventive services delivered by a health care practitioner in an office, clinic, or health care system. Other examples include genetic testing or assessments, physical rehabilitation, tobacco cessation counseling or nicotine replacement therapy, case management, primary prevention clinical assessments, and family history screening.
- Education Services: Number of evidence-based, culturally appropriate cancer prevention and control education and outreach services delivered to the public and to health care professionals. Examples include education or training sessions (group or individual), focus groups, and knowledge assessments.
- Evidence-Based Program: A program that is validated by some form of documented research or applied evidence. CPRIT's website provides links to resources for evidence-based strategies, programs, and clinical recommendations for cancer prevention and control. To access this information, visit
 http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control.
- Goals: Broad statements of general purpose to guide planning. Goals should be few in number and focus on aspects of highest importance to the project.
- **Integration:** The extent the evidence-based intervention is integrated within the culture of the grantee's setting or community through policies and practice.
- Navigation Services: Number of unique activities/services that offer assistance to help
 overcome health care system barriers in a timely and informative manner and facilitate
 cancer screening and diagnosis to improve health care access and outcomes. Examples
 include patient reminders, transportation assistance, and appointment scheduling
 assistance.

- **Objectives:** Specific, **measurable**, actionable, realistic, and timely projections for outputs and outcomes; example: "Increase screening service provision in X population from Y% to Z% by 20xx." Baseline data for the priority population must be included as part of each objective.
- **People Reached:** Number of members of the public and/or professionals reached via noninteractive public or professional education and outreach activities, such as mass media efforts, brochure distribution, public service announcements, newsletters, and journals. This category includes individuals who would be reached through activities that are directly funded by CPRIT as well as individuals who would be reached through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project.
- People Served: Number of members of the public and/or professionals served via direct, interactive public or professional education, outreach, training, navigation service delivery, or clinical service delivery, such as live educational and/or training sessions, vaccine administration, screening, diagnostics, case management/navigation services, and physician consults. This category includes individuals who would be served through activities that are directly funded by CPRIT as well as individuals who would be served through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project (e.g., X people screened for cervical cancer after referral to Y indigent care program as a result of CPRIT-funded navigation services performed by the project).

Third Party Observer Reports



CPRIT Peer Review Meeting Observation Report

Report #2015-09-21/22-PRE

Program Name: Prevention

Panel Name: FY16.1 Prevention Peer Review Panel - 1

Panel Date: September 21, 2015 to September 22, 2015

Report Date: September 30, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Peer Review Panel-1 peer review of applications for FY16 funding. The meeting was co-chaired by Ross Brownson and Nancy Lee and held at the Hyatt Regency in Dallas TX on September 21 through September 22, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Prevention Peer Review Panel-1 panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and co-chaired by Ross Brownson and Nancy Lee on September 21 through September 22, 2015.

The independent observer noted the following during our observation:

- Sixteen applications were discussed within the Prevention Peer Review Meeting Panel to determine
 which grants would receive CPRIT funding.
- Eleven peer review panelists, two advocate reviewers, four CPRIT staff members and five SRA
 employees were present on September 21, 2015. Eleven peer review panelists, two advocate reviewers,
 three CPRIT staff members and five SRA employees were present on September 22, 2015.
- Eight conflicts of interest were identified prior to or during the meeting. Applications for seven
 conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest either
 left the room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Prevention Review Council Meeting Observation Report

Report #2015-10-23-PREV

Program Name: Prevention

Panel Name: FY16.1 Prevention Review Council

Programmatic Review

Panel Date: October 23, 2015 Report Date: October 29, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Review Council Programmatic Review peer review of applications for FY16 funding. The meeting was chaired by Stephen Wyatt and held via teleconference on October 23, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Prevention Review Council Programmatic Review held via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Stephen Wyatt on October 23, 2015.

The independent observer noted the following during our observation:

- Sixteen applications were discussed within the Prevention Review Council Meeting to determine which
 grants would receive CPRIT funding.
- Three peer review panelists, two CPRIT staff members and one SRA employee were present for the meeting.
- One conflict of interest was identified prior to or during the meeting. Applications for one conflict was
 discussed during the peer review panel. The reviewer with the conflict of interest either left the room
 or did not participate telephonically and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Prevention Cycle 16.1 Applications (Prevention Cycle 16.1 Awards Announced at November 19, 2015, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Prevention Cycle 16.1 include Cancer Prevention Promotion and Navigation to Clinical Services, Competitive Continuation/Expansion—Evidence-Based Cancer Prevention Services, Evidence-Based Cancer Prevention Services, Evidence-Based Cancer Prevention Services - Colorectal Cancer Prevention Coalition, and Dissemination of CPRIT-Funded Cancer Prevention and Control Interventions. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted
Applica	tions considered by the	e PIC and Oversight Co	mmittee
PP160023	Sauter, Edward	The University of Texas Health Center at Tyler	Schwartz, Randy; Cole, Kirk
PP160027	Foxhall, Lewis	The University of Texas M.D. Anderson Cancer Center	Vanderpool, Robin; Cole, Kirk
PP160042	Parra-Medinca, Deborah	The University of Texas Health Science Center at San Antonio	Vanderpool, Robin
PP160046	Cuccaro, Paula	The University of Texas Health Science Center at Houston	Vanderpool, Robin
PP160047	Savas, Lara	The University of Texas Health Science Center at Houston	Brownson, Ross
PP160048	Bolin, Jane	Texas A&M University System Health Science Center	Escabedo, Luis; Cole, Kirk
PP160051	Fernandez, Maria	Texas A&M University System	Cole, Kirk

Application ID	Applicant	Institution	Conflict Noted							
		Health Science								
		Center								
Applications Not Recommended for PIC or Oversight Committee Consideration										
PP160026	Handal, Gilbert	Texas Tech	Escobedo, Luis							
		University Health								
		Sciences Center at El								
		Paso								
PP160043	Gonzalez, Hector	City of Laredo Health	Escobedo, Luis							
		Department								

De-Identified Overall Evaluation Scores

Evidence-Based Cancer Prevention Services

Prevention Cycle 16.1

Application ID	Final Overall Evaluation Score
PP160046 ¹	2.20
PP160042*	2.80
PP160010*	3.10
bb	3.50
PP160027*	3.50

See "Final Overall Evaluation Scores and Rank Order Scores" section for explanation by Prevention Review Council of recommendation out of score order.

¹ PP160046 was recommended by the Prevention Review Council and deferred to a future Program Integration Committee meeting by the Program Integration Committee members.

^{*=}Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

Pete Geren
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to pgcprit@sidrichardson.org

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Mr. Roberts and Mr. Geren,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for CPRIT Prevention grant awards. The applicants on the attached list of submitted proposals responded to CPRIT requests for applications (RFA) released for the first review cycle of FY2016. These recommendations reflect 50+ hours of work by individual reviewers and include panel discussion of the applicants' proposals, in addition to the PRC's programmatic review.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are provided for each grant application. The PRC did not make changes to the goals, timelines, or project objectives requested by the applicants. When the PRC did not follow the rank ordered scores in developing its recommended funding order a justification, based upon established programmatic priorities outlined in the RFAs, is provided.

The projected funding available for this fiscal year is \$27,965,885. However, the recent interpretation that annual prevention program funding is 10% of the CPRIT awarded dollars within a fiscal year could impact the dollars available. With the second funding cycle for the fiscal year underway, the PRC opted for a conservative approach to its recommendations for this cycle. Recommendations are provided at two levels: (1) initially fund 12 projects totaling an estimated \$13,247,742 and (2) depending upon the availability of funds later in the fiscal year, fund an additional 2 projects (PP160046 and PP160033 totaling \$2,999,657).

Our recommendations meet the PRC's standards for grant award funding of projects that are evidence-based, deliver programs or services to underserved populations, and focus on primary, secondary or tertiary prevention. In making these recommendations the PRC also considered the available funding, the composition of the current portfolio, and the programmatic priorities in the RFA which include potential for impact and return on investment, geographic distribution, cancer type and type of program. All of the recommended grants address one or more of the Prevention Program priorities.

Sincerely,

Stephen W. Wyatt, DMD, MPH Chair, CPRIT Prevention Review Council

App ID	Mech ·	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP16004 9	CCE- EBP	Expansion of a comprehensive cervical cancer screening program for medically underserved women in Harris County	Anderson, Matthew L	Baylor College of Medicine	\$1,500,000	1.9			1	
PP16004 7	CCE- EBP	A community based program to increase breast and cervical cancer screening and HPV vaccination to reduce the impact of breast and certical cancer among Latinas	Savas, Lara S	The University of Texas Health Science Center at Houston	\$1,387,005	2.7	Steps that will be taken to assess actual # of screenings and vaccinations for participants in educational sessions are not explained. It appears that only women completing the surveys will be followed. Evaluation of outcomes for all participants is not provided, only provided for women completing surveys. Budget is unclear about number of screenings that will be paid for; number of financially supported	Changes not recommended-PRC reviewed peer review comments and determined those comments did NOT impact decision to recommend or impact rank order	2	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							screening isn't clearly stated.			
PP16004 2	EBP	Using Best Practices to Promote HPV vaccination in Rural Primary Care Settings	Parra- Medina, Deborah	The University of Texas Health Science Center at San Antonio	\$1,295,493	2.8	Outcomes evaluation doesn't have baseline and % increase noted. A highly intensive program is being implemented and the high cost is a barrier. If the cost is reduced, the applicability of the proposed approach may be enhanced. Reviewers would like the applicants to clarify why the increase in the budget from the previous grant to this grant. Why has the per person	changes not recommended- PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	3	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							cost increased so much?			
PP16003 2	PN	Family Health History-based Colorectal Cancer Prevention and Navigation to Clinical Services among Uninsured Chinese Americans in Texas	Chen, Lei- Shih	Texas A&M University	\$399,993	3.0	Findings from this study should be applied to follow-up treatment for the participants. Plans for this are lacking and should be provided.	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	4	
PP16005 6	PN	REACH Rural Education and Awareness for Community Health	Hoelscher, Bill	Coastal Bend Wellness Foundatio n	\$379,698	3.0	Should be clarified that \$25 gift card is not being offered to change the behavior of the participants.	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	5	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP16001 0	EBP	Maximizing opportunities for HPV vaccination in the Golden Triangle	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	\$1,409,909	3.1	Ask applicants why they do not plan to vaccinate young adults on college campuses. In addition, students could be used to help with recruitment	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	6	
PP16004 8	DI	Training CHWs for More Effective Cancer Education and Navigation	Bolin, Jane N	Texas A&M University System Health Science Center	\$300,000	3.1			7	
PP16002 3	EBP- CRC	Optimizing Colorectal Cancer Screening in East Texas	Sauter, Edward	The University of Texas Health Center at Tyler	\$2,299,753	3.3	Recommendation was made in previous application that providing FIT isn't evidence-based for people who are at significant risk for CRC; this isn't consistent with ACS guidelines. Ask how they came up with \$275/colonoscopy	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	8	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP16003 6	CCE- EBP	Establishing a Comprehensiv e Cancer Prevention and Support Program within Asian American Communities in Houston and Austin Areas of Texas	Sun, Helen	Light and Salt Associatio n	\$1,101,986	3.3	Request that the applicant provides a leadership plan that includes input from the three communities being targeted: Vietnames, Korean, and Filipino	changes not recommended-PRC reveiwed peer review comments and determined they did not impact decision to recommend or impact rank order	9	
PP16002 7	EBP	Improving Service Delivery to Cancer Survivors in Primary Care Settings	Foxhall, Lewis E	The University of Texas M. D. Anderson Cancer Center	\$1,374,127	3.5	Not clear how project will add to what is already happening in clinic. This is a large, complex project and not clear how it will be managed on a daily basis. Budget is weak and justification for some of the positions is lacking	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	10	Recommende d out of score order above one with higher score due to ROI and cancer type
PP16005 1	DI	Dissemination of an Evidence- Based HPV Vaccination Intervention in Community and Clinical Settings	Fernandez , Maria E	The University of Texas Health Science Center at Houston	\$299,778	3.6	List of current awards doesn't specify PD participation; it should be verified that PD isn't overcommitted. Budget seems somewhat personnel heavy and accounts for a	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	11	Recommende d out of score order above one with higher score due to type of program

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							large majority of voerall costs; careful review of personnel and their exact roles and responsibilities and whether or not any of the services are duplicative may be warranted.			
PP16001 1	CCE- EBP	GRACIAS Texas: Genetic Risk Assessment for Cancer in All South Texas	Tomlinson , Gail E	The University of Texas Health Science Center at San Antonio	\$1,500,000	2.7			12	Recommende d but ranked out of score order due to 1) ROI may be limited; large numbers need to be screened to identify at risk pop.
PP16004 6	ЕВР	Using social marketing and mobile school-based vaccination clinics to increase HPV vaccination uptake in highrisk geographic areas	Cuccaro, Paula	The University of Texas Health Science Center at Houston	\$1,499,668	2.2			13	Recommende d but out of score order due to 1) geography- several HPV grants in Harris county, 2) ROI-costs for education vs services

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP16003	CCE- EBP	Increasing cancer control behaviors among the underserved: A collaboration with Texas 2-1-1 programs	Fernandez , Maria E	The University of Texas Health Science Center at Houston	\$1,499,989	2.4			14	Recommende d but out of score order due to 1) geography- several HPV grants in Harris county, 2) cancer type- availabilty of breast and cervical services 3) ROI-costs for education vs services
				Initial funding (Rank #1- 12)	\$13,247,74 2					
				(Rank #13+14)	\$2,999,657					
				2nd funding	\$16,247,39 9					



CEO Affidavit Supporting Information

FY 2016—Cycle 1
Evidence-Based Cancer Prevention Services - Colorectal
Cancer Prevention Coalition

Request for Applications



REQUEST FOR APPLICATIONS RFA P-16-EBP-CRC-1

Evidence-Based Cancer Prevention Services Colorectal Cancer Prevention Coalition

Please also refer to the "Instructions for Applicants" document, which will be posted April 30, 2015

Application Receipt Opening Date: April 16, 2015

Application Receipt Closing Date: July 9, 2015

FY 2016

September 1, 2015-August 31, 2016

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RFA VERSION HISTORY

Rev 4/16/15 RFA release

1. ABOUT CPRIT

The state of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the state of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Prevention Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The Prevention Program's principles and priorities will also guide CPRIT staff and the Prevention Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

Established Principles:

- Fund evidence-based interventions and their dissemination
- Support the prevention continuum of primary, secondary and tertiary (includes survivorship) prevention interventions

Prevention Program Priorities

- Prioritize populations and areas of greatest need, greatest potential for impact
- Focus on underserved populations
- Increase targeting of preventive efforts to areas where significant disparities in cancer incidence or mortality in the state exist

2. FUNDING OPPORTUNITY DESCRIPTION

2.1. Summary

The ultimate goals of the CPRIT Prevention Program are to reduce overall cancer incidence and mortality and to improve the lives of individuals who have survived or are living with cancer. The ability to reduce cancer death rates depends in part on the application of currently available evidence-based technologies and strategies. CPRIT will foster the primary, secondary, and tertiary prevention of cancer in Texas by providing financial support for a wide variety of evidence-based risk reduction, early detection, and survivorship interventions.

The Evidence-Based Cancer Prevention Services Colorectal Cancer Prevention Coalition (EBP-CRC) award mechanism seeks to fund projects that greatly challenge the status quo in colorectal cancer prevention and control services. The proposed project should be designed to reach and serve as many people as possible. Partnerships with organizations that can provide clinical services (i.e., clinics, hospitals, Federally Qualified Health Centers) are required. In addition to partnerships with clinical service providers, partnerships with other organizations that can support and leverage resources (i.e., community-based organizations, local and voluntary agencies, nonprofit agencies, groups that represent priority populations) are strongly encouraged. A coordinated submission of a collaborative coalition in which all partners have a substantial role in the proposed project is required.

The intent of this mechanism is to maximize the impact of the project by its simultaneous implementation in multiple clinical sites. Collaboration with clinical services organizations must be executed in a coordinated manner so that access to care and utilization of services are increased. The clinical service provider partners should all provide the same education, navigation, and clinical services. The intent is not to have the various sites providing different services or subsets of services.

2.2. Project Objectives

CPRIT seeks to fund projects that will do the following:

• Deliver evidence-based comprehensive colorectal cancer prevention services aimed at reducing health disparities in colorectal cancer screening, incidence, and mortality.

- Increase screening rates among persons 50 years and older and those at high risk (as defined by the American Cancer Society)¹ in identified service regions; focusing on asymptomatic persons with CRC, those who have not been screened before, and those who have inadequate or no health insurance coverage for CRC screening.
- Coordinate clinical service providers and other partners to create a coalition with the goal
 of screening and treating (for cancers or precancers detected) the most counties and the
 most people possible in a selected service region. For those identified with colorectal
 cancer or precancer through the screening exam who do not have health insurance
 coverage, assurance of appropriate treatment must be provided.
- Implement system changes to decrease wait time between positive screen and diagnostic test (navigation, reminder systems, etc.) and treatment. Offer systems and/or policy changes that are sustainable over time.
- Deliver uniform services, data collection, and reporting from the coalition.

2.3. Award Description

This Request for Applications (RFA) solicits applications for projects up to 36 months in duration that will deliver a comprehensive and integrated colorectal cancer screening project that includes provision of screening, diagnostic, and navigation services in conjunction with outreach and education of the target population through a coalition of partners.

The following are required project elements:

Comprehensive projects. Comprehensive projects include a continuum of services and systems and policy changes and comprise all or some of the following: Public and professional education and training, outreach, delivery of screening and diagnostic services, followup navigation, data collection and tracking, and systems improvement.

This mechanism will fund case management/patient navigation to screening, to diagnostic testing, and to treatment. Applicants must ensure that there is access to treatment services for patients with cancers or precancers that are detected as a result of the project and must describe the process for ensuring access to treatment services in their application.

Applicants should not request funds for all of the above components if they already are being paid from other sources.

Evidence Based. CPRIT's service grants are intended to fund effective and efficient systems of delivery of prevention services based on the existing body of knowledge about and evidence for cancer prevention in ways that far exceed current performance in a given service area;

- Applicants may select the types of colorectal cancer screening tests offered but should be limited to those recommended by the US Preventive Services Task Force (USPSTF).²
- Education and outreach strategies to support patient recruitment may include small media activities and one-on-one outreach or other methods known to be effective in reaching the project's priority population.³
- If evidence-based strategies have not been implemented or tested for the specific population or service setting proposed, provide evidence that the proposed service is appropriate for the population and has a high likelihood of success.
- Baseline data (e.g., availability of resources and screening coverage) for the target
 population and target service region are required. If no baseline data exist, the applicant
 must present clear plans and describe method(s) of measurement used to collect the data
 necessary to establish a baseline.

Clinical service provider and community partner coalitions. The applicant should coordinate and describe a collaboration of clinical service providers that can deliver outreach, education, screening, and navigation services to the most counties and the most people possible in a selected service region. In addition, partnerships with other organizations that can support and leverage resources (i.e., community-based organizations, local and voluntary agencies, nonprofit agencies, groups that represent priority populations, etc.) are strongly encouraged. The applicant should coordinate and describe a coalition in which all partners have a substantial role in the proposed project. Letters of commitment or memoranda of understanding describing their role in the partnership are required from all clinical service providers and participating organizations.

Project Coordination and Technical Assistance. The overall screening program should be directed and overseen by the Program Director who is responsible for establishing and managing an integrated and collaborative coalition of clinical service providers and other community partners. A leader at each clinical project site is required and should be designated with a title of "Project Lead."

- The Program Director must establish any necessary subcontracts or memoranda of understanding with project partners and clinical service providers.
- The Program Director must facilitate the establishment of standard protocols for all clinical service providers in the coalition (e.g., offering choice of test options, such as fecal immunochemical test [FIT] first, FIT/Flu), as well as standard systems, policies, and procedures for the participating clinical service providers and organizations. These include, but are not limited to, patient tracking and timely followup of all abnormal screening results and/or diagnoses of cancer.
- The Program Director must also provide means to regularly communicate with Project
 Leads to discuss progress and barriers, resolve potential problems, and provide technical
 assistance as needed throughout the duration of the project.
- The Program Director is responsible for all reporting requirements. CPRIT expects measurable outcomes of supported activities, such as a significant increase over baseline (for the proposed service area) in the provision of evidence-based services, changes in provider practice, systems changes, and cost-effectiveness. The applicant should project a realistic and feasible 3-year increase in the CRC screening rate.

Under this RFA, CPRIT will not consider the following:

- Projects focusing solely on systems and/or policy change or solely on education and/or outreach that do not include the delivery of services
- Projects focusing solely on case management/patient navigation services. Case management/patient navigation services must be paired with the delivery of a clinical service. Furthermore, while navigation to the point of treatment of cancer is required when cancer is discovered through a CPRIT-funded project, applications seeking funds to provide coordination of care while an individual is in treatment are not allowed under this RFA.

2.3.1. Priorities

Types of Cancer: Only projects proposing prevention and early detection of colorectal cancer and precancer will be considered.

Target Populations: The age of the target population and frequency of screening plans for provision of clinical services described in the application must comply with established and current national guidelines of the USPSTF.

Priority populations are subgroups that are disproportionately affected by cancer. CPRIT-funded efforts must address 1 or more of these priority populations:

- Underinsured and uninsured individuals
- Geographically or culturally isolated populations
- Medically unserved or underserved populations
- Racial, ethnic, and cultural minority populations
- Populations with low screening rates, high incidence rates, and high mortality rates, focusing on individuals never before screened.

2.3.2. Specific Areas of Emphasis

Data compiled by the Texas Cancer Registry on colorectal cancer highlight needs in the following areas:

- Increasing screening/detection rates in Health Service Regions (HSRs) 1 through 6 and HSR 9. For more information about maps of HSRs, please visit http://www.dshs.state.tx.us/regions/state.shtm
 - The highest rates of cancer incidence mortality are found in these regions of Texas.⁴
- Decreasing disparities in incidence and mortality rates of colorectal cancer for racial/ethnic populations and rural communities.
 - African Americans have the highest incidence and mortality rates, followed by non-Hispanic whites and Hispanics.⁴
- Decreasing incidence and mortality rates in rural counties.
 - Incidence and mortality rates are higher in rural counties compared to urban counties.⁴

2.3.3. Outcome Metrics

The applicant is required to describe final outcome measures for the project. Interim measures that are associated with the final outcome measures should be identified and will serve as a

measure of program effectiveness and public health impact. Applicants are required to clearly describe their assessment and evaluation methodology. **Baseline data for each measure proposed are required**. In addition, applicants should describe how funds from the CPRIT grant will improve outcomes over baseline. If the applicant is not providing baseline data for a measure, the applicant must provide a well-justified explanation and describe clear plans and method(s) of measurement used to collect the data necessary to establish a baseline.

Reporting Requirements

Funded projects are required to report quantitative output and outcome metrics through the submission of quarterly progress reports, annual reports, and a final report.

- Quarterly progress report sections include, but are not limited to the following:
 - Narrative on project progress, including formation and management of the coalition, (required)
 - People reached through project activities
 - o Services, other than clinical services, provided to the public/professionals
 - Actions taken by people/professionals as a result of education or training, including percentage of people reporting sustained behavior change
 - Clinical services provided
 - Abnormal results and precursors or cancers detected
- Annual and Final progress report sections include, but are not limited to the following:
 - Key accomplishments, including the following:
 - Qualitative analysis of policy change and/or lasting systems change
 - Effectiveness of the coalition
 - Progress against goals and objectives, including percentage increase over baseline in provision of age- and risk-appropriate comprehensive preventive services to eligible men and women in a defined service area; for example:
 - Percentage increase over baseline in number of people served
 - Percentage increase over baseline in number of services provided
 - Percentage increase over baseline in cancers and precancers detected
 - Percentage increase in early-stage cancer diagnoses in a defined service area
 - Percentage increase in navigation to treatment

- Materials produced and publications
- Economic impact of the project

2.4. Eligibility

- The applicant must be a Texas-based entity, such as a community-based organization, health institution, government organization, public or private company, college or university, or academic health institution.
- The designated Project Director (PD) will be responsible for the overall performance of the funded project. The PD must have relevant education and management experience and must reside in Texas during the project performance time.
- The evaluation of the project must be headed by a professional who has demonstrated expertise in the field (e.g., qualitative or quantitative statistics) and who resides in Texas during the time that the project is conducted.
- The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant may submit more than 1 application, but each application must be for
 distinctly different services without overlap in the services provided. Applicants who do
 not meet this criterion will have all applications administratively withdrawn without peer
 review.
- The PD or coalition partners may have a current CPRIT grant for CRC screening but must describe how this new grant complements their current grant. Outcomes and progress on the current grant must be described in the Grants Summary form (See Section 4.4.9). Organizations that have current CRC screening grants may also opt to transition their current project to a new coalition grant if awarded. Funds cannot be transferred from one project to another. The CPRIT Prevention Program will work with the PD of the current grant to provide guidance and ensure a smooth transition.

- Additional collaborations are permitted and encouraged, and collaborators may or may
 not reside in Texas. However, collaborators who do not reside in Texas are not eligible to
 receive CPRIT funds. Subcontracting and collaborating organizations may include
 public, not-for-profit, and for-profit entities. Such entities may be located outside of the
 state of Texas, but non-Texas-based organizations are not eligible to receive CPRIT
 funds.
- An applicant organization is eligible to receive a grant award only if the applicant certifies that the applicant organization, including the PD, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), have not made and will not make a contribution to CPRIT or to any foundation created to benefit CPRIT.
- The applicant must report whether the applicant organization, the PD, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, (whether slated to receive salary or compensation under the grant award or not), are currently ineligible to receive federal grant funds because of scientific misconduct or fraud or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. CPRIT grants are funded on a reimbursement-only basis. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in Section 6. All statutory provisions and relevant administrative rules can be found at http://www.cprit.state.tx.us.

2.4.1. Resubmission Policy

More than **1 resubmission** is not permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PD for a project, or a change of title for a project that was previously submitted to

CPRIT does not constitute a new application; the application would be considered a resubmission.

2.5. Funding Information

CPRIT expects that funding requests will vary depending on the proposed geographic coverage and number of people served. Applicants may request any amount of funding over a maximum of 36 months.

Grant funds may be used to pay for clinical services, navigation services, salary and benefits, project supplies, equipment, costs for outreach and education of populations, and travel of project personnel to project site(s). Requests for funds to support construction, renovation, or any other infrastructure needs or requests to support lobbying will not be approved under this mechanism. Grantees may request funds for travel for 2 project staff to attend CPRIT's conference.

The budget should be proportional to the number of individuals receiving programs and services, and a significant proportion of funds is expected to be used for program delivery as opposed to program development. In addition, CPRIT seeks to fill gaps in funding rather than replace existing funding, supplant funds that would normally be expended by the applicant's organization, or make up for funding reductions from other sources.

3. KEY DATES

RFA

RFA release April 16, 2015

Application

Online application opens April 30, 2015, 7 AM central time

Application due July 9, 2015, 3 PM central time

Application review September 2015

Award

Award notification November 2015
Anticipated start date December 2015

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

4. APPLICATION SUBMISSION GUIDELINES

4.1. Instructions for Applicants document

It is imperative that applicants read the accompanying instructions document for this RFA (https://CPRITGrants.org). Requirements may have changed from previous versions.

4.2. Online Application Receipt System

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be considered eligible for evaluation. The PD must create a user account in the system to start and submit an application. The Co-PD, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on April 30, 2015, and must be submitted by 3 PM central time on July 9, 2015. Detailed instructions for submitting an application are in the *Instructions for Applicants* document, posted on CARS. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

4.3. Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via email to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

4.4. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements will be administratively withdrawn without review.

4.4.1. Abstract and Significance (5,000 characters)

Clearly explain the problem(s) to be addressed, the approach(es) to the solution, and how the application is responsive to this RFA. In the event that the project is funded, the abstract will be made public; therefore, no proprietary information should be included in this statement. Initial compliance decisions are based in part upon review of this statement.

The required abstract format is as follows (use headings as outlined below):

- Need: Include a description of need in the specific service area. Include rates of
 incidence, mortality, and screening in the service area compared to overall Texas rates.
 Describe barriers, plans to overcome these barriers, and the target population to be
 served.
- Overall Project Strategy: Describe the project and how it will address the identified need. Clearly explain what the project is and what it will specifically do, including the services to be provided and the process/system for delivery of services and outreach to the targeted population.
- **Specific Goals:** State specifically the overall goals of the proposed project; include the estimated overall numbers of people (public and/or professionals) reached and people (public and/or professionals) served.
- **Innovation:** Describe the creative components of the proposed project and how it differs from current programs or services being provided.
- **Significance and Impact:** Explain how the proposed project, if successful, will have a unique and major impact on cancer prevention and control for the population proposed to be served and for the state of Texas.

4.4.2. Goals and Objectives

List specific goals and **measurable** objectives for each year of the project. A baseline and method(s) of measurement are required for each objective. Provide both raw numbers and percent changes for the baseline and target. Applicants must explain plans to establish baseline and describe method(s) of measurement in cases where a baseline has not been defined.

4.4.3. Project Timeline

Provide a project timeline for project activities that includes deliverables and dates. Use Years 1, 2, 3 and months 1,2,3, etc., as applicable instead of specific months or years (e.g., Year 1, Months 3-5, not 2017, March – May).

4.4.4. Project Plan (30 pages maximum; fewer pages permissible)

The required project plan format follows. Applicants must use the headings outlined below. Applications not following the required format will be administratively withdrawn.

Background: Briefly present the rationale behind the proposed service, emphasizing the critical barriers to current service delivery that will be addressed. Identify the evidence-based service to be implemented for the target population. If evidence-based strategies have not been implemented or tested for the specific population or service setting proposed, provide evidence that the proposed service is appropriate for the population and has a high likelihood of success. Baseline data for the target population and target service area are required where applicable. Reviewers will be aware of national and state statistics, and these should be used only to compare rates for the proposed service area. Describe the geographic region of the state that the project will serve; maps are appreciated.

Goals and Objectives (optional): Goals and Objectives will be entered in separate fields in CARS and need not be provided in the project plan. However, if desired, goals and objectives may be fully repeated or briefly summarized here.

Components of the Project: Clearly describe the need, delivery method, and evidence base (provide references) for the services as well as anticipated results. Describe why this project is nonduplicative, creative, or unique.

Clearly describe the coalition, its structure, key personnel and their experience, resources and facilities available from each partner, and plans to leverage existing funding and infrastructure. Also describe plans for management and technical support to the coalition including monitoring, communications, data collection, and reporting.

Clearly demonstrate the ability to provide the proposed service, describe how results will be improved over baseline and the ability to reach the target population. Applicants must also clearly describe plans to ensure access to treatment services should cancer be detected.

List in table format the types and number of each education service, navigation service, and clinical service (See <u>Appendix</u> for definitions) to be delivered. In addition, list the TOTAL number of all services. Treatment services are not appropriate for this award mechanism and should not be included.

Evaluation Strategy: A strong commitment to evaluation of the project is required. Describe the impact on ultimate outcome measures and interim outcome measures as outlined in Section 2.3.3. Describe the plan for outcome measurements, including data collection and management methods, statistical analyses, and anticipated results. Evaluation and reporting of outcomes must be headed by a professional who has demonstrated expertise in the field of program evaluation, intervention science, cancer screening, and/or behavioral risk reduction. If needed, applicants may want to consider seeking expertise at Texas-based academic cancer centers, schools/programs of public health, prevention research centers, or the like. Applicants should budget accordingly for the evaluation activity and should involve that professional during grant application preparation to ensure, among other things, that the evaluation plan is linked to the proposed goals and objectives.

Organizational Qualifications and Capabilities: Describe the organization and its track record and success in providing programs and services. Include information on the organization's financial stability and viability. Describe the role and qualifications of the key collaborators/partners in the project. Applicants must demonstrate that they have provider partnerships and agreements (via memoranda of understanding) or commitments (via letters of commitment) in place.

Integration and Capacity Building: CPRIT funds projects that target the unmet needs not sufficiently covered by other funding sources, and full maintenance of the project may not be feasible. This is especially the case when the project involves the delivery of clinical services. Educational and other less costly interventions may be more readily sustained. Full maintenance of a project, the ability of the grantee's setting or community to continue to deliver the health benefits of the intervention as funded, is not required; however, efforts toward maintenance should be described.

It is expected that steps toward integration and capacity building for components of the project will be taken and plans for such be fully described in the application. *Integration* is defined as the extent the evidence-based intervention is integrated within the culture of the grantee's setting or community through policies and practice. *Capacity building* is any activity (e.g., training, identification of alternative resources, building internal assets) that builds durable resources and enables the grantee's setting or community to continue the delivery of some or all components of the evidence-based intervention.

Elements of integration and capacity building may include, but are not limited to, the following:

- Developing ownership, administrative networks, and formal engagements with stakeholders
- Developing processes for each practice/location to incorporate services into its structure beyond project funding
- Identifying and training of diverse resources (human, financial, material, and technological)
- Implementing policies to improve effectiveness and efficiency (including costeffectiveness) of systems

Dissemination and Scalability (Expansion): Describe how the project lends itself to dissemination to or application by other communities and/or organizations in the state or expansion in the same communities. Describe plans for dissemination of positive and negative project results and outcomes. Dissemination of project results and outcomes, including barriers encountered and successes achieved, is critical to building the evidence base for cancer prevention and control efforts in the state. Dissemination methods may include, but are not limited to, presentations, publications, abstract submissions, and professional journal articles, etc.

4.4.5. People Reached (complete online)

Provide the estimated overall number of people (members of the public and professionals) to be reached by the funded project. The applicant is required to itemize separately the types of noninteractive education and outreach activities, with estimates, that led to the calculation of the overall estimates provided. Refer to the Appendix for definitions.

4.4.6. People Served (complete online)

Provide the estimated overall number of people (members of the public and professionals) to be served by the funded project. The applicant is required to itemize separately the education, navigation, and clinical activities/services, with estimates, that led to the calculation of the overall estimates provided. Refer to the <u>Appendix</u> for definitions.

4.4.7. References

Provide a concise and relevant list of references cited for the application. The successful applicant will provide referenced evidence and literature support for the proposed services.

4.4.8. Resubmission Summary (if applicable; download template)

Describe the approach to the resubmission and how reviewers' comments were addressed. The summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission; the applicant is not responsible for providing this document.

4.4.9. CPRIT Grants Summary (download template)

Provide a description of the progress or final results of **all** CPRIT-funded projects of the PD or Co-PD, regardless of their connection to this application. Indicate how the current application builds on the previous work or addresses new areas of cancer prevention and control services. Applications that are missing this document and for which CPRIT records show a PD and/or Co-PD with previous or current CPRIT funds will be administratively withdrawn.

4.4.10. Budget and Justification (complete online)

Provide a brief outline and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, travel, equipment, supplies, contractual expenses, services delivery, and other expenses. CPRIT funds will be distributed on a reimbursement basis.

Cost Per Person Served: The cost per person served will be automatically calculated
from the total cost of the project divided by the total number of people (both public and
professionals) served (refer to <u>Appendix</u>). A significant proportion of funds is expected to
be used for program delivery as opposed to program development and organizational
infrastructure.

- **Personnel:** The individual salary cap for CPRIT awards is \$200,000 per year. Describe the source of funding for all project personnel where CPRIT funds are not requested.
- **Travel:** PDs and related project staff are expected to attend CPRIT's conference. CPRIT funds may be used to send up to 2 people to the conference.
- Equipment: Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application. Justification must be provided for why funding for this equipment cannot be found elsewhere; CPRIT funding should not supplant existing funds. Cost sharing of equipment purchases is strongly encouraged.
- **Services Costs:** CPRIT reimburses for services using Medicare reimbursement rates. Describe the source of funding for all services where CPRIT funds are not requested.

Other Expenses

- o **Incentives:** Use of incentives or positive rewards to change or elicit behavior is allowed; however, incentives may only be used based on strong evidence of their effectiveness for the purpose and in the target population identified by the applicant. CPRIT will not fund cash incentives. The maximum dollar value allowed for an incentive per person, per activity or session, is \$25.
- Indirect Costs: It is CPRIT's policy not to allow recovery of indirect costs for prevention projects.
- Costs Not Related to Cancer Prevention and Control: CPRIT does not allow recovery of any costs for services not related to cancer (e.g., health physicals, HIV testing).

4.4.11. Current and Pending Support and Sources of Funding (download template)

Describe the funding source and duration of all current and pending support for the proposed project, including a capitalization table that reflects private investors, if any.

4.4.12. Biographical Sketches (download template)

The designated PD will be responsible for the overall performance of the funded project and must have relevant education and management experience. The PD/Co-PD(s) must provide a

biographical sketch that describes his or her education and training, professional experience, awards and honors, and publications and/or involvement in programs relevant to cancer prevention and/or service delivery.

The evaluation professional must provide a biographical sketch.

Each Project Lead must provide a biographical sketch. Up to 10 additional biographical sketches, including the project lead biosketches, for key personnel may be provided. Each biographical sketch must not exceed 2 pages.

Only biographical sketches will be accepted; do not submit resumes and/or CVs.

4.4.13. Collaborating Organizations (complete online)

List all key participating organizations that will partner with the applicant organization to provide 1 or more components essential to the success of the project (e.g., evaluation, clinical services, recruitment to screening).

4.4.14. Letters of Commitment

Applicants should provide letters of commitment and/or memoranda of understanding from community organizations, key faculty, or any other component essential to the success of the project.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively withdrawn without review.

5. APPLICATION REVIEW

5.1. Review Process Overview

All eligible applications will be reviewed using a 2-stage peer review process: (1) evaluation of applications by peer review panels and (2) prioritization of grant applications by the Prevention Review Council. In the first stage, applications will be evaluated by an independent review panel using the criteria listed below. In the second stage, applications judged to be meritorious by review panels will be evaluated by the Prevention Review Council and recommended for funding based on comparisons with applications from all of the review panels and programmatic

priorities. Programmatic considerations may include, but are not limited to, geographic distribution, cancer type, population served, and type of program or service. The scores are only 1 factor considered during programmatic review. At the programmatic level of review, priority will be given to proposed projects that target geographic regions of the state or population subgroups that are not well represented in the current CPRIT Prevention project portfolio.

Applications approved by Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

Each stage of application review is conducted confidentially, and all CPRIT Peer Review Panel members, Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Peer Review Panel members and Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer Review Panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee Member, a PIC Member, a Review Panel member, or a Review Council

member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

5.2. Review Criteria

Peer review of applications will be based on primary scored criteria and secondary unscored criteria, identified below. Review panels consisting of experts in the field and advocates will evaluate and score each primary criterion and subsequently assign an overall score that reflects an overall assessment of the application. The overall evaluation score will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application and responsiveness to the RFA priorities.

5.2.1. Primary Evaluation Criteria

Impact and Innovation

- Do the proposed services address an important problem or need in colorectal cancer prevention and control? Do the proposed project strategies support desired outcomes in cancer incidence, morbidity, and/or mortality? Does the proposed project demonstrate creativity, ingenuity, resourcefulness, or imagination? Does it take evidence-based interventions and apply them in innovative ways to explore new partnerships, new audiences, or improvements to systems?
- Does the project address adaptation, if applicable, of the evidence-based intervention to the target population?
- Does the project address known gaps in prevention services and avoid duplication of effort?

- Does the proposed coalition demonstrate that the collaborative effort will provide a
 greater impact on colorectal cancer prevention and control than the applicant
 organization's effort separately?
- Will the project reach and serve an appropriate number of people based on the budget allocated to providing services and the cost of providing services?

Project Strategy and Feasibility

- Does the proposed project provide services specified in the RFA?
- Are the overall project approach, strategy, and design clearly described and supported by established theory and practice?
- Are the proposed objectives and activities feasible within the duration of the award? Has the applicant convincingly demonstrated the short- and long-term impacts of the project?
- Are possible barriers addressed and approaches for overcoming them proposed?
- Are the target population and culturally appropriate methods to reach the target population clearly described?
- Does the coordinating organization demonstrate the ability to provide coordination, monitoring, reporting, and technical assistance to the coalition?
- Does the applicant demonstrate the availability of coalition resources and expertise to provide comprehensive services including case management, followup for abnormal results, and access to treatment?
- Does the project leverage partners and resources to maximize the reach of the services proposed? Does the project leverage and complement other state, federal, and nonprofit grants?

Outcomes Evaluation

- Are specific goals and measurable objectives for each year of the project provided?
- Are the proposed outcome measures appropriate for the services provided, and are the expected changes clinically significant?
- Does the application provide a clear and appropriate plan for data collection and management, statistical analyses, and interpretation of results to follow, measure, and report on the project's outcomes?

- Are clear baseline data provided for the proposed goals and objectives, or are clear plans included to collect baseline data?
- If an evidence-based intervention is being adapted in a population where it has not been implemented or tested, are plans for evaluation of barriers, effectiveness, and fidelity to the model described?
- Is a qualitative analysis or process evaluation of the effectiveness of the coalition as well as policy or system changes described?

Organizational Qualifications and Capabilities

- Do the organization and its collaborators/partners demonstrate the ability to provide the proposed preventive services? Does the described role of each collaborating organization make it clear that each organization adds value to the project and is committed to working together to implement the project?
- Have the appropriate personnel been recruited to implement, evaluate, and complete the project?
- Is the organization structurally and financially stable and viable?

Integration and Capacity Building

- Does the applicant describe steps that will be taken and components of the project that will be integrated into the organization through policies and practices?
- Does the applicant describe steps that will be taken or components of the project that will remain (e.g., trained personnel, identification of alternative resources, building internal assets) to continue the delivery of <u>some or all</u> components of the evidence-based intervention once CPRIT funding ends.

5.2.2. Secondary Evaluation Criteria

Budget

- Is the budget appropriate and reasonable for the scope and services of the proposed work?
- Is the cost per person served appropriate and reasonable?
- Is the proportion of the funds allocated for direct services reasonable?
- Is the project a good investment of Texas public funds?

Dissemination and Scalability

- Are plans for dissemination of the project's results and outcomes, including barriers encountered and successes achieved, clearly described?
- Does the project or do some components of the project lend themselves to scalability/expansion by others in the state? If so, does the application describe a plan for doing so?

6. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. Applicants are advised to review CPRIT's administrative rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires the PD of the award to submit quarterly, annual, and final progress reports. These reports summarize the progress made toward project goals and address plans for the upcoming year and performance during the previous year(s). In addition, quarterly fiscal reporting and reporting on selected metrics will be required per the instructions to award

recipients. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of award contract.

7. CONTACT INFORMATION

7.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding the scope and focus of applications. Before contacting the HelpDesk, please refer to the *Instructions for Applicants* document (posted by April 30, 2015), which provides a step-by-step guide to using CARS.

Dates of operation: April 30, 2015, to July 9, 2015 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time

Wednesday, 8 AM to 4 PM central time

Tel: 866-941-7146

Email: Help@CPRITGrants.org

7.2. Program Questions

Questions regarding the CPRIT Prevention program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Prevention Program Office.

Tel: 512-305-8422

E-mail: <u>Help@CPRITGrants.org</u>

Website: www.cprit.state.tx.us

8. RESOURCES

- The Texas Cancer Registry: http://www.dshs.state.tx.us/tcr
- The Community Guide http://www.thecommunityguide.org/index.html
- Cancer Control P.L.A.N.E.T. http://cancercontrolplanet.cancer.gov
- Guide to Clinical Preventive Services: Recommendations of the U.S. Preventive Services
 Task Force. http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/
- Brownson, RC, Colditz GA, and Proctor, EK (Editors). Dissemination and Implementation Research in Health: Translating Science to Practice. Oxford University Press, March 2012.
- Centers for Disease Control and Prevention: The Program Sustainability Assessment
 Tool: A New Instrument for Public Health Programs
 http://www.cdc.gov/pcd/issues/2014/13 0184.htm
- Centers for Disease Control and Prevention: Using the Program Sustainability Tool to Assess and Plan for Sustainability http://www.cdc.gov/pcd/issues/2014/13 0185.htm

9. REFERENCES

- 1. http://www.cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancer-moreinformation/colonandrectumcancer-moreinformation/colonandrectumcancer-moreinformation/colonandrectumcancer-moreinformation/colonandrectumcancer-moreinformation/colonandrectumcancer-moreinformation/colonandrectumcancer-moreinformation/colonandrectumcancer-moreinformation/colonandrectumcancer-moreinformation/colonandrectumcancer-moreinformation/colonandrectumcancer-moreinformation/colonandrectumcancer-moreinformation/colonandrectumcancer-moreinformation/colonandrectumcancer-moreinformation/colonandrectumcancer-moreinformation/colorectal-cancer-early-detection-acs-recommendations-moreinformation-mor
- 2. http://www.uspreventiveservicestaskforce.org/uspstf/uspscolo.htm
- 3. http://www.thecommunityguide.org/cancer/index.html
- 4. Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas

 Department of State Health Services http://www.dshs.state.tx.us/tcr/default.shtm

10. APPENDIX: KEY TERMS

- **Activities:** A listing of the "who, what, when, where, and how" for each objective that will be accomplished.
- Capacity Building: Any activity (e.g., training, identification of alternative resources, building internal assets) that builds durable resources and enables the grantee's setting or

- community to continue the delivery of <u>some or all</u> components of the evidence-based intervention.
- Clinical Services: Number of clinical services such as screenings, diagnostic tests, vaccinations, counseling sessions, or other evidence-based preventive services delivered by a health care practitioner in an office, clinic, or health care system. Other examples include genetic testing or assessments, physical rehabilitation, tobacco cessation counseling or nicotine replacement therapy, case management, primary prevention clinical assessments, and family history screening.
- Education Services: Number of evidence-based, culturally appropriate cancer prevention and control education and outreach services delivered to the public and to health care professionals. Examples include education or training sessions (group or individual), focus groups, and knowledge assessments.
- Evidence-Based Program: A program that is validated by some form of documented research or applied evidence. CPRIT's website provides links to resources for evidence-based strategies, programs, and clinical recommendations for cancer prevention and control. To access this information, visit
 http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control.
- **Goals:** Broad statements of general purpose to guide planning. Goals should be few in number and focus on aspects of highest importance to the project.
- **Integration:** The extent the evidence-based intervention is integrated within the culture of the grantee's setting or community through policies and practice.
- Navigation Services: Number of unique activities/services that offer assistance to help
 overcome health care system barriers in a timely and informative manner and facilitate
 cancer screening and diagnosis to improve health care access and outcomes. Examples
 include patient reminders, transportation assistance, and appointment scheduling
 assistance.
- **Objectives:** Specific, **measurable**, actionable, realistic, and timely projections for outputs and outcomes; example: "Increase screening service provision in X population from Y% to Z% by 20xx." Baseline data for the target population must be included as part of each objective.

- People Reached: Number of members of the public and/or professionals reached via noninteractive public or professional education and outreach activities, such as mass media efforts, brochure distribution, public service announcements, newsletters, and journals. This category includes individuals who would be reached through activities that are directly funded by CPRIT as well as individuals who would be reached through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project.
- People Served: Number of members of the public and/or professionals served via direct, interactive public or professional education, outreach, training, navigation service delivery, or clinical service delivery, such as live educational and/or training sessions, vaccine administration, screening, diagnostics, case management/navigation services, and physician consults. This category includes individuals who would be served through activities that are directly funded by CPRIT as well as individuals who would be served through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project (e.g., X people screened for cervical cancer after referral to Y indigent care program as a result of CPRIT-funded navigation services performed by the project).

Third Party Observer Reports



CPRIT Peer Review Meeting Observation Report

Report #2015-09-21/22-PRE

Program Name: Prevention

Panel Name: FY16.1 Prevention Peer Review Panel - 1

Panel Date: September 21, 2015 to September 22, 2015

Report Date: September 30, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Peer Review Panel-1 peer review of applications for FY16 funding. The meeting was co-chaired by Ross Brownson and Nancy Lee and held at the Hyatt Regency in Dallas TX on September 21 through September 22, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Prevention Peer Review Panel-1 panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and co-chaired by Ross Brownson and Nancy Lee on September 21 through September 22, 2015.

The independent observer noted the following during our observation:

- Sixteen applications were discussed within the Prevention Peer Review Meeting Panel to determine
 which grants would receive CPRIT funding.
- Eleven peer review panelists, two advocate reviewers, four CPRIT staff members and five SRA
 employees were present on September 21, 2015. Eleven peer review panelists, two advocate reviewers,
 three CPRIT staff members and five SRA employees were present on September 22, 2015.
- Eight conflicts of interest were identified prior to or during the meeting. Applications for seven
 conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest either
 left the room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Prevention Review Council Meeting Observation Report

Report #2015-10-23-PREV

Program Name: Prevention

Panel Name: FY16.1 Prevention Review Council

Programmatic Review

Panel Date: October 23, 2015 Report Date: October 29, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Review Council Programmatic Review peer review of applications for FY16 funding. The meeting was chaired by Stephen Wyatt and held via teleconference on October 23, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Prevention Review Council Programmatic Review held via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Stephen Wyatt on October 23, 2015.

The independent observer noted the following during our observation:

- Sixteen applications were discussed within the Prevention Review Council Meeting to determine which
 grants would receive CPRIT funding.
- Three peer review panelists, two CPRIT staff members and one SRA employee were present for the meeting.
- One conflict of interest was identified prior to or during the meeting. Applications for one conflict was
 discussed during the peer review panel. The reviewer with the conflict of interest either left the room
 or did not participate telephonically and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Prevention Cycle 16.1 Applications (Prevention Cycle 16.1 Awards Announced at November 19, 2015, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Prevention Cycle 16.1 include Cancer Prevention Promotion and Navigation to Clinical Services, Competitive Continuation/Expansion—Evidence-Based Cancer Prevention Services, Evidence-Based Cancer Prevention Services, Evidence-Based Cancer Prevention Services - Colorectal Cancer Prevention Coalition, and Dissemination of CPRIT-Funded Cancer Prevention and Control Interventions. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted	
Applications considered by the PIC and Oversight Committee				
PP160023	Sauter, Edward	The University of Texas Health Center at Tyler	Schwartz, Randy; Cole, Kirk	
PP160027	Foxhall, Lewis	The University of Texas M.D. Anderson Cancer Center	Vanderpool, Robin; Cole, Kirk	
PP160042	Parra-Medinca, Deborah	The University of Texas Health Science Center at San Antonio	Vanderpool, Robin	
PP160046	Cuccaro, Paula	The University of Texas Health Science Center at Houston	Vanderpool, Robin	
PP160047	Savas, Lara	The University of Texas Health Science Center at Houston	Brownson, Ross	
PP160048	Bolin, Jane	Texas A&M University System Health Science Center	Escabedo, Luis; Cole, Kirk	
PP160051	Fernandez, Maria	Texas A&M University System	Cole, Kirk	

Application ID	Applicant	Institution	Conflict Noted		
		Health Science			
		Center			
Applications Not Recommended for PIC or Oversight Committee Consideration					
PP160026	Handal, Gilbert	Texas Tech	Escobedo, Luis		
		University Health			
		Sciences Center at El			
		Paso			
PP160043	Gonzalez, Hector	City of Laredo Health	Escobedo, Luis		
		Department			

De-Identified Overall Evaluation Scores

Evidence-Based Cancer Prevention Services- Colorectal Cancer Prevention Coalition

Prevention Cycle 16.1

Application ID	Final Overall Evaluation Score
PP160023*	3.0

^{*=}Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

Pete Geren
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to pgcprit@sidrichardson.org

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Mr. Roberts and Mr. Geren,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for CPRIT Prevention grant awards. The applicants on the attached list of submitted proposals responded to CPRIT requests for applications (RFA) released for the first review cycle of FY2016. These recommendations reflect 50+ hours of work by individual reviewers and include panel discussion of the applicants' proposals, in addition to the PRC's programmatic review.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are provided for each grant application. The PRC did not make changes to the goals, timelines, or project objectives requested by the applicants. When the PRC did not follow the rank ordered scores in developing its recommended funding order a justification, based upon established programmatic priorities outlined in the RFAs, is provided.

The projected funding available for this fiscal year is \$27,965,885. However, the recent interpretation that annual prevention program funding is 10% of the CPRIT awarded dollars within a fiscal year could impact the dollars available. With the second funding cycle for the fiscal year underway, the PRC opted for a conservative approach to its recommendations for this cycle. Recommendations are provided at two levels: (1) initially fund 12 projects totaling an estimated \$13,247,742 and (2) depending upon the availability of funds later in the fiscal year, fund an additional 2 projects (PP160046 and PP160033 totaling \$2,999,657).

Our recommendations meet the PRC's standards for grant award funding of projects that are evidence-based, deliver programs or services to underserved populations, and focus on primary, secondary or tertiary prevention. In making these recommendations the PRC also considered the available funding, the composition of the current portfolio, and the programmatic priorities in the RFA which include potential for impact and return on investment, geographic distribution, cancer type and type of program. All of the recommended grants address one or more of the Prevention Program priorities.

Sincerely,

Stephen W. Wyatt, DMD, MPH Chair, CPRIT Prevention Review Council

App ID	Mech ·	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP16004 9	CCE- EBP	Expansion of a comprehensive cervical cancer screening program for medically underserved women in Harris County	Anderson, Matthew L	Baylor College of Medicine	\$1,500,000	1.9			1	
PP16004 7	CCE- EBP	A community based program to increase breast and cervical cancer screening and HPV vaccination to reduce the impact of breast and certical cancer among Latinas	Savas, Lara S	The University of Texas Health Science Center at Houston	\$1,387,005	2.7	Steps that will be taken to assess actual # of screenings and vaccinations for participants in educational sessions are not explained. It appears that only women completing the surveys will be followed. Evaluation of outcomes for all participants is not provided, only provided for women completing surveys. Budget is unclear about number of screenings that will be paid for; number of financially supported	Changes not recommended-PRC reviewed peer review comments and determined those comments did NOT impact decision to recommend or impact rank order	2	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							screening isn't clearly stated.			
PP16004 2	EBP	Using Best Practices to Promote HPV vaccination in Rural Primary Care Settings	Parra- Medina, Deborah	The University of Texas Health Science Center at San Antonio	\$1,295,493	2.8	Outcomes evaluation doesn't have baseline and % increase noted. A highly intensive program is being implemented and the high cost is a barrier. If the cost is reduced, the applicability of the proposed approach may be enhanced. Reviewers would like the applicants to clarify why the increase in the budget from the previous grant to this grant. Why has the per person	changes not recommended- PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	3	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							cost increased so much?			
PP16003 2	PN	Family Health History-based Colorectal Cancer Prevention and Navigation to Clinical Services among Uninsured Chinese Americans in Texas	Chen, Lei- Shih	Texas A&M University	\$399,993	3.0	Findings from this study should be applied to follow-up treatment for the participants. Plans for this are lacking and should be provided.	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	4	
PP16005 6	PN	REACH Rural Education and Awareness for Community Health	Hoelscher, Bill	Coastal Bend Wellness Foundatio n	\$379,698	3.0	Should be clarified that \$25 gift card is not being offered to change the behavior of the participants.	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	5	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP16001 0	EBP	Maximizing opportunities for HPV vaccination in the Golden Triangle	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	\$1,409,909	3.1	Ask applicants why they do not plan to vaccinate young adults on college campuses. In addition, students could be used to help with recruitment	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	6	
PP16004 8	DI	Training CHWs for More Effective Cancer Education and Navigation	Bolin, Jane N	Texas A&M University System Health Science Center	\$300,000	3.1			7	
PP16002 3	EBP- CRC	Optimizing Colorectal Cancer Screening in East Texas	Sauter, Edward	The University of Texas Health Center at Tyler	\$2,299,753	3.3	Recommendation was made in previous application that providing FIT isn't evidence-based for people who are at significant risk for CRC; this isn't consistent with ACS guidelines. Ask how they came up with \$275/colonoscopy	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	8	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP16003 6	CCE- EBP	Establishing a Comprehensiv e Cancer Prevention and Support Program within Asian American Communities in Houston and Austin Areas of Texas	Sun, Helen	Light and Salt Associatio n	\$1,101,986	3.3	Request that the applicant provides a leadership plan that includes input from the three communities being targeted: Vietnames, Korean, and Filipino	changes not recommended-PRC reveiwed peer review comments and determined they did not impact decision to recommend or impact rank order	9	
PP16002 7	EBP	Improving Service Delivery to Cancer Survivors in Primary Care Settings	Foxhall, Lewis E	The University of Texas M. D. Anderson Cancer Center	\$1,374,127	3.5	Not clear how project will add to what is already happening in clinic. This is a large, complex project and not clear how it will be managed on a daily basis. Budget is weak and justification for some of the positions is lacking	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	10	Recommende d out of score order above one with higher score due to ROI and cancer type
PP16005 1	DI	Dissemination of an Evidence- Based HPV Vaccination Intervention in Community and Clinical Settings	Fernandez , Maria E	The University of Texas Health Science Center at Houston	\$299,778	3.6	List of current awards doesn't specify PD participation; it should be verified that PD isn't overcommitted. Budget seems somewhat personnel heavy and accounts for a	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	11	Recommende d out of score order above one with higher score due to type of program

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							large majority of voerall costs; careful review of personnel and their exact roles and responsibilities and whether or not any of the services are duplicative may be warranted.			
PP16001 1	CCE- EBP	GRACIAS Texas: Genetic Risk Assessment for Cancer in All South Texas	Tomlinson , Gail E	The University of Texas Health Science Center at San Antonio	\$1,500,000	2.7			12	Recommende d but ranked out of score order due to 1) ROI may be limited; large numbers need to be screened to identify at risk pop.
PP16004 6	EBP	Using social marketing and mobile school-based vaccination clinics to increase HPV vaccination uptake in highrisk geographic areas	Cuccaro, Paula	The University of Texas Health Science Center at Houston	\$1,499,668	2.2			13	Recommende d but out of score order due to 1) geography- several HPV grants in Harris county, 2) ROI-costs for education vs services

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP16003	CCE- EBP	Increasing cancer control behaviors among the underserved: A collaboration with Texas 2-1-1 programs	Fernandez , Maria E	The University of Texas Health Science Center at Houston	\$1,499,989	2.4			14	Recommende d but out of score order due to 1) geography- several HPV grants in Harris county, 2) cancer type- availabilty of breast and cervical services 3) ROI-costs for education vs services
				Initial funding (Rank #1- 12)	\$13,247,74 2					
				(Rank #13+14)	\$2,999,657					
				2nd funding	\$16,247,39 9					



CEO Affidavit Supporting Information

FY 2016—Cycle 1
Individual Investigator Research Awards

Request for Applications



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS RFA R-16-IIRA-1

Individual Investigator Research Awards

Please also refer to the Instructions for Applicants document, which will be posted on March 20, 2015

Application Receipt Opening Date: March 20, 2015 **Application Receipt Closing Date:** May 20, 2015

FY 2016

Fiscal Year Award Period September 1, 2015-August 31, 2016

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RFA VERSION HISTORY

Rev 02/20/15 RFA release

1. ABOUT CPRIT

The state of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the state of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The principles and priorities of the Scientific Research program will guide CPRIT staff, peer reviewers, and the Scientific Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs. The program priorities for research adopted by the Oversight Committee include funding projects that address:

- A broad range of innovative, investigator-initiated research projects;
- Prevention and early detection;
- Rare and intractable cancers, including childhood cancers;
- Cancers of importance in Texas;
- Computational biology and analytic methods; and
- Building Infrastructure.

2. RATIONALE

The goals of the CPRIT Research Grants Program are to support the discovery of new information about cancer that can lead to prevention, early detection, and cures and to translate new and existing discoveries into practical advances in cancer diagnosis and treatment. CPRIT encourages applications that seek new fundamental knowledge about cancer and cancer

development as well as those attempting to develop state-of-the-art technologies, tools, computational models, and/or resources for cancer research, including those with potential commercialization opportunities. This award allows experienced or early career–stage cancer researchers the opportunity to explore new methods and approaches for investigating a question of importance that has been inadequately addressed or for which there may be an absence of an established paradigm or technical framework. CPRIT will look with special favor on new approaches to be taken or new areas of investigation to be explored by established investigators and on supporting the research programs of the most promising investigators at the beginning of their research careers. Applicants need not be trained specifically in cancer research. Indeed, CPRIT strongly encourages investigators from other fields, including the mathematical and computational modeling, physical, chemical, and engineering sciences, to bring their expertise to bear on the exceptionally challenging problems posed by cancer. CPRIT expects outcomes of supported activities to directly and indirectly benefit subsequent cancer research efforts, cancer public health policy, or the continuum of cancer care—from prevention to treatment and cure.

To fulfill this vision, applications may address any topic or issue related to cancer, including cancer biology, computational modeling, and systems biology, causation, prevention, detection or screening, treatment, or cure. Successful applicants should be working in a research environment capable of supporting potentially high-impact studies. Access to a clinical environment and interaction with translational cancer physician-scientists are highly desirable.

3. RESEARCH OBJECTIVES

CPRIT will foster cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research. This Request for Applications (RFA) solicits applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. The goal of awards made in response to this RFA is to fund exceptionally innovative research projects with great potential impact that are directed by a single investigator. Areas of interest include laboratory research, translational studies, and/or clinical investigations. Applications that include collaboration with computational modeling teams are welcomed. In that cancers arise from a large number of derangements of basic molecular and cellular functions and, in turn, cause many alterations in basic biological processes, almost any aspect of biology may be relevant to cancer research, more or less directly. The *degree of relevance* to cancer research will be an important criterion for evaluation of projects for funding by CPRIT (section 9.4.1). For example, are alterations in the process in question *primarily* responsible for oncogenesis or secondary

manifestations of malignant transformation? Will understanding the process or interfering with it offer selective and useful insight into prevention, diagnosis, or treatment of cancer? *Successful applicants for funding from CPRIT will have addressed these questions satisfactorily.*

4. FUNDING INFORMATION

Applicants may request a maximum of \$300,000 in total costs per year for up to 3 years for research. Exceptions to these limits may be requested if extremely well justified (see section 8.2.10). Applications funded in this cycle will be eligible for competitive renewal. Funds may be used for salary and fringe benefits, research supplies, equipment, subject participation costs, and travel to scientific/technical meetings or collaborating institutions. Requests for funds to support construction and/or renovation will not be approved under this funding mechanism. State law limits the amount of award funding that may be spent on indirect costs to no more than 5% of the total award amount.

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization
 that conducts research is eligible to apply for funding under this award mechanism.

 A public or private company is not eligible for funding under this award mechanism;
 these entities must use the appropriate award mechanism(s) under CPRIT's Product
 Development Program.
- The Principal Investigator (PI) must have a doctoral degree, including MD, PhD, DDS,
 DMD, DrPH, DO, DVM, or equivalent, and must reside in Texas during the time the research that is the subject of the grant is conducted.
- A PI may not submit applications to this RFA and to RFA-R-16-IIRACB-1, RFA-R-16-IIRACCA-1, or RFA R-16-IIRAP-1. Only 1 IIRA, IIRACB, IIRACCA, or IIRAP application per cycle is allowed. A PI may submit only 1 new or resubmission application under this RFA during this funding cycle. If submitting a renewal application, a PI may submit both a new or resubmission application and a renewal application under this RFA during this funding cycle. An investigator who is the PI on 3 or more CPRIT grants of any type that will be active December 1, 2015 is not eligible to submit an application in response to this RFA.
- Applications that address Prevention and Early Detection, Cancers in Children and Adolescents, or Computational Biology should be submitted under the appropriate targeted RFA.

- Because this award mechanism is intended to support research directed by a single investigator, only 1 Co-PI may be included.
- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Collaborators should have specific and well-defined roles. Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the state of Texas, but non—Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PI, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the PI, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds, or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. RESUBMISSION POLICY

An application previously submitted to CPRIT but not funded may be resubmitted once and must follow all resubmission guidelines. More than 1 resubmission is not permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PI for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission. This policy is in effect for all applications submitted to date. See section 8.2.5.

7. RENEWAL POLICY

An application funded by CPRIT under this mechanism may be submitted for a competitive renewal. This policy is in effect for all awards submitted to date. See <u>section 8.2.6</u>. Competitive renewals are not subject to preliminary evaluation. Renewal applications move directly to the full peer review phase. See <u>section 9.2</u>.

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and submit an application. The Co-PI, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (ASO) (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on March 20, 2015, and must be submitted by 3 PM central time on May 20, 2015. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

8.1.1. Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via email to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in <u>section 5</u> will be administratively withdrawn without review.

8.2.1. Abstract and Significance (5,000 characters)

Clearly explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the Research Plan.

Clearly address how the proposed project, if successful, will have a major impact on cancer. Summarize how the proposed research creates new paradigms or challenges existing ones. Indicate whether this research plan represents a new direction for the PI.

Note: It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance statement alone. Therefore, applicants are advised to prepare this section wisely. Applicants should not waste this valuable space by stating obvious facts (eg, that cancer is a significant problem; that better diagnostic and therapeutic approaches are needed urgently; or that the type of cancer of interest to the PI is important, vexing, or deadly). Based on this statement (and the Budget and Justification and Biographical Sketches), applications that are judged to offer only modest contributions to the field of cancer research or that do not sufficiently capture the reviewers' interest may be excluded from further peer review (see section 9.1).

8.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer research, early diagnosis, prevention, or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Do not include any proprietary information in the Layperson's Summary. The Layperson's Summary will also be used by advocate reviewers (section 9.2) in evaluating the significance and impact of the proposed work.

8.2.3. Goals and Objectives

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success.

8.2.4. Timeline (1 page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications.

If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.5. Resubmission Summary (1 page)

Applicants preparing a resubmission must describe the approach to the resubmission. If a summary statement was prepared for the original application review, applicants are advised to address all noted concerns.

Note: An application previously submitted to CPRIT but not funded may be resubmitted once after careful consideration of the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a fresh Research Plan or modify the original Research Plan and mark the changes. However, all resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

8.2.6. Renewal Summary (2 pages)

Applicants preparing a renewal must describe and demonstrate that appropriate/adequate progress has been made on the current funded award to warrant further funding. Publications and manuscripts in press that have resulted from work performed during the initial funded period should be listed in the renewal summary.

8.2.7. Research Plan (10 pages)

Background: Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed.

Hypothesis and Specific Aims: Concisely state the hypothesis and/or specific aims to be tested or addressed by the research described in the application.

Research Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data that support the proposed hypothesis are encouraged but not required.

8.2.8. Vertebrate Animals and/or Human Subjects (1 page)

If vertebrate animals will be used, provide an outline of the appropriate protocols that will be followed. If human subjects or human biological samples will be used, provide a plan for recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism.

8.2.9. Publications/References

Provide a concise and relevant list of publications/references cited for the application.

8.2.10. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. Applicants are advised not to interpret the maximum allowable request under this award as a suggestion that they should expand their anticipated budget to this level. Reasonable budgets clearly work in favor of the applicant.

However, if there is a highly specific and defensible need to request more than the maximum amount in any year(s) of the proposed budget, include a special and clearly labeled section in the budget justification that explains the request. Poorly justified requests of this type will likely have a negative impact on the overall evaluation of the application.

In preparing the requested budget, applicants should be aware of the following:

- Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. So-called grants management and facilities fees (eg, sponsored programs fees; grants and contracts fees; electricity, gas, and water; custodial fees; maintenance fees) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.
- The annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2016 is \$200,000; CPRIT FY 2016 is from September 1, 2015, through August 31, 2016. Salary does not include fringe benefits and/or facilities and administrative (F&A) costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

8.2.11. Biographical Sketches (2 pages each)

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. A biographical sketch must be provided for the PI and, if applicable, the Co-PI (as required by the online application receipt system). Up to 2 additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed 2 pages.

8.2.12. Current and Pending Support

Describe the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title, a 2-line summary of the goal of the project, and, if relevant, a statement of overlap with the current application. At a minimum, current and pending support of the PI and, if applicable, the Co-PI must be provided.

8.2.13. Institutional/Collaborator Support and/or Other Certification (4 pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 4 pages may be provided.

8.2.14. Previous Summary Statement

If the application is being resubmitted, the summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission. The applicant is not responsible for providing this document.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively rejected without review.

9. APPLICATION REVIEW

9.1. Preliminary Evaluation

To ensure the timely and thorough review of only the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, all eligible applications may be preliminarily evaluated by CPRIT Scientific Research Program panel members for scientific merit and impact.

This preliminary evaluation will be based on a subset of material presented in the application—namely Abstract and Significance, Budget and Justification, and Biographical Sketches. Applications that do not sufficiently capture the reviewers' interest at this stage will not be considered for further review. Such applications will have been judged to offer only modest contributions to the field of cancer research and will be excluded from further peer review.

The applicant will be notified of the decision to disapprove the application after the preliminary evaluation stage has concluded. Due to the volume of applications to be reviewed, comments made by reviewers at the preliminary evaluation stage may not be provided to applicants. The preliminary evaluation process will be used only when the number of applications exceeds the capacity of the review panels to conduct a full peer review of all received applications.

9.2. Full Peer Review

Applications that pass preliminary evaluation will undergo further review using a 2-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts as well as advocate reviewers using the criteria listed below. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by Scientific Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

9.3. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Peer Review Panel members and Scientific Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. **By submitting** a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee Member, a PIC Member, a Scientific Review Panel member, or a Scientific Review Council member. Applicants should note that the CPRIT Program Integration Committee comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

9.4. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.

9.4.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study. Primary criteria include the following:

Significance and Impact: Will the results of this research, if successful, significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for patients? Is the application innovative? Does the applicant propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or

resources for cancer research or address important underexplored or unexplored areas? If the

research project is successful, will it lead to truly substantial advances in the field rather than add

modest increments of insight? Projects that modestly extend current lines of research will not be

considered for this award. Projects that represent straightforward extensions of ongoing work,

especially work traditionally funded by other mechanisms, will not be competitive.

Research Plan: Is the proposed work presented as a self-contained research project? Does the

proposed research have a clearly defined hypothesis or goal that is supported by sufficient

preliminary data and/or scientific rationale? Are the methods appropriate, and are potential

experimental obstacles and unexpected results discussed?

Applicant Investigator: Does the applicant investigator demonstrate the required creativity and

expertise to make a significant contribution to the research? Applicants' credentials will be

evaluated in a career stage-specific fashion. Have early career-stage investigators received

excellent training, and do their accomplishments to date offer great promise for a successful

career? Has the applicant devoted a sufficient amount of his or her time (percentage effort) to

this project?

Relevance: Does the proposed research have a high degree of relevance to cancer research? This

will be an important criterion for evaluation of projects for CPRIT support.

9.4.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these

criteria potentially question the feasibility of the proposed research.

Secondary criteria include the following:

Research Environment: Does the research team have the needed expertise, facilities, and

resources to accomplish all aspects of the proposed research? Are the levels of effort of the key

personnel appropriate? Is there evidence of institutional support of the research team and the

project?

Vertebrate Animals and/or Human Subjects: If vertebrate animals and/or human subjects are

included in the proposed research, certification of approval by the institutional IACUC and/or

IRB, as appropriate, will be required before funding can occur.

Budget: Is the budget appropriate for the proposed work?

Duration: Is the stated duration appropriate for the proposed work?

CPRIT RFA R-16-IIRA-1

10. KEY DATES

RFA

RFA release February 20, 2015

Application

Online application opens March 20, 2015, 7 AM central time

Application due May 20, 2015, 3 PM central time

Application review September - October 2015

Award

Award notification November 2015

Anticipated start date March 2016

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In

addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed, and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements regarding demonstration of available funding.

13. CONTACT INFORMATION

13.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding scientific aspects of applications.

Dates of operation: February 20 – May 20, 2015 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time

Wednesday, 8 AM to 4 PM central time

Tel: 866-941-7146

Email: <u>Help@CPRITGrants.org</u>

13.2. Scientific and Programmatic Ouestions

Questions regarding the CPRIT program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Senior Manager for Research.

Tel: 512-305-8491

Email: Help@CPRITGrants.org

Website: www.cprit.state.tx.us

Third Party Observer Report



CPRIT Research Peer Review Observation Report

Report #2015-09-29-RES

Program Name: Academic Research

Panel Name: FY16.1 Clinical & Translational Cancer

Research and Translational Cancer Research

Panel Date: September 29, 2015 Report Date: October 7, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Clinical & Translational Cancer Research and Translational Cancer Research peer review of applications for FY16 funding. The meeting was co-chaired by Richard O'Reilly and Margaret Tempero and held at the Marriott Suites Medical/Market Center in Dallas TX on September 29, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Clinical & Translational Cancer Research and Translational Cancer Research panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and co-chaired by Richard O'Reilly and Margaret Tempero on September 29, 2015.

The independent observer noted the following during our observation:

- Twenty-four applications were discussed within the Research Peer Review Meeting to determine which
 grants would receive CPRIT funding.
- Twenty-six peer review panelists, three advocate reviewers, three CPRIT staff members and five SRA employees were present for the meeting.
 - o Two of the twenty-six peer review panelists participated via teleconference.
- Thirteen conflicts of interest were identified prior to or during the meeting. Applications for nine
 conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest either
 left the room or did not participate telephonically and did not participate in the review of the conflicted
 application.
 - One of the nine conflicts did not sign out on the conflict of interest sign out sheet when leaving the room.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Research Peer Review Observation Report

Report #2015-09-30-RES

Program Name: Academic Research

Panel Name: FY16.1 Cancer Prevention Research

Panel Date: September 30, 2015 Report Date: October 7, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Cancer Prevention Research peer review of applications for FY16 funding. The meeting was chaired by Tom Sellers and held at the Marriott Suites Medical/Market Center in Dallas TX on September 30, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Cancer Prevention Research panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Tom Sellers on September 30, 2015.

The independent observer noted the following during our observation:

- Nineteen applications were discussed within the Research Peer Review Meeting to determine which
 grants would receive CPRIT funding.
- Seventeen peer review panelists, two advocate reviewers, four CPRIT staff members and five SRA
 employees were present for the meeting.
 - One of the seventeen peer review panelists participated via teleconference and for only one application.
- Twenty-one conflicts of interest were identified prior to or during the meeting. Applications for fifteen
 conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest either
 left the room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical
or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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CPRIT Research Peer Review Observation Report

Report #2015-10-01-RES

Program Name: Academic Research

Panel Name: FY16.1 Imaging Technology and

Informatics

Panel Date: October 1, 2015 Report Date: October 7, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Imaging Technology and Informatics peer review of applications for FY16 funding. The meeting was chaired by Sam Gambhir and held at the Marriott Suites Medical/Market Center in Dallas TX on October 1, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Imaging Technology and Informatics panel meeting held inperson. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Sam Gambhir on October 1, 2015.

The independent observer noted the following during our observation:

- Eighteen applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Twenty-one peer review panelists, two advocate reviewers, two CPRIT staff members and five SRA
 employees were present for the meeting.
 - One of the twenty-one peer review panelists participated via teleconference.
- Five conflicts of interest were identified prior to or during the meeting. Applications for two conflicts
 were discussed during the peer review panel. The reviewers with the conflicts of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Research Peer Review Observation Report

Report #2015-10-05-RES

Program Name: Academic Research

Panel Name: FY16.1 Basic Cancer Research 2

Panel Date: October 5, 2015 Report Date: October 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Basic Cancer Research 2 peer review of applications for FY16 funding. The meeting was chaired by Carol Prives and held at the Marriott Suites Medical/Market Center in Dallas TX on October 5, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Basic Cancer Research 2 panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Carol Prives on October 5, 2015.

The independent observer noted the following during our observation:

- Nineteen applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Fifteen peer review panelists, two advocate reviewers, two CPRIT staff members, five SRA employees
 and chair for the Scientific Review Council were present for the meeting.
 - o Two of the fifteen peer review panelists participated via teleconference.
 - One participated for review of only four applications and the other participated as an ad hoc reviewer for one application.
- Two conflicts of interest were identified prior to or during the meeting. Applications for one conflict
 was discussed during the peer review panel. The reviewer with the conflict of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
 - o The reviewer was present when final scores were still visible on projection screen.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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CPRIT Research Peer Review Observation Report

Report #2015-10-06-RES

Program Name: Academic Research

Panel Name: FY16.1 Basic Cancer Research 1

Panel Date: October 6, 2015 Report Date: October 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Basic Cancer Research 1 peer review of applications for FY16 funding. The meeting was chaired by Tom Curran and held at the Marriott Suites Medical/Market Center in Dallas TX on October 6, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Basic Cancer Research 1 panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Tom Curran on October 6, 2015.

The independent observer noted the following during our observation:

- Thirty applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Eighteen peer review panelists, two advocate reviewers, three CPRIT staff members and six SRA employees were present for the meeting.
 - One of the eighteen peer review panelists participated via teleconference.
 - One of the two advocate reviewers participated via teleconference.
- Two conflicts of interest were identified prior to or during the meeting. Applications for one conflict
 was discussed during the peer review panel. The reviewer with the conflict of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical
or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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CPRIT Research Peer Review Observation Report

Report #2015-10-07-RES

Program Name: Academic Research

Panel Name: FY16.1 Cancer Biology

Panel Date: October 7, 2015 Report Date: October 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Cancer Biology peer review of applications for FY16 funding. The meeting was chaired by Peter Jones and held at the Marriott Suites Medical/Market Center in Dallas TX on October 7, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Cancer Biology panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Peter Jones on October 7, 2015.

The independent observer noted the following during our observation:

- Twenty-two applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Fifteen peer review panelists, two advocate reviewers, two CPRIT staff members and five SRA
 employees were present for the meeting.
 - o Two of the fifteen peer review panelists participated via teleconference.
- Seven conflicts of interest were identified prior to or during the meeting. Applications for five conflicts
 were discussed during the peer review panel. The reviewers with the conflicts of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Scientific Review Council Meeting Observation Report

Report #2015-10-23-RES

Program Name: Academic Research

Panel Name: FY16.1 Scientific Review Council

Meeting

Panel Date: October 23, 2015 Report Date: October 27, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Scientific Review Council Meeting peer review of applications for FY16 funding. The meeting was chaired by Richard Kolodner and held via teleconference on October 23, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Scientific Review Council Meeting held via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Richard Kolodner on October 23, 2015.

The independent observer noted the following during our observation:

- Over the course of the call, a review of the scoring for the 65 recommended applications was completed to ensure that they would in fact be recommended for funding. A score cut-off was reinforced by the panel as to which applications will move forward.
- Six peer review panelists, two CPRIT staff members and one SRA employee were present for the meeting.
- No conflicts of interest were identified prior to or during the meeting.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Academic Research Cycle 16.1 Applications (Academic Research Cycle 16.1 Awards Announced at November 19, 2015 Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Cycle 16.1 include Individual Investigator Research Awards, Individual Investigator Research Awards for Prevention and Early Detection, Individual Investigator Research Awards for Cancer in Children and Adolescents, Individual Investigator Research Awards for Computational Biology, and Research Training Awards. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted
App	Applications considered by the PIC and Oversight Committee		
RP160183pe/ RP160183	Davies, Michael	The University of Texas M. D. Anderson Cancer Center	McMahon, Martin
RP160471pe/ RP160471	Draetta, Giulio	The University of Texas M. D. Anderson Cancer Center	Courtneidge, Sara
RP160013pe/ RP160013	Kundra, Vikas	The University of Texas M. D. Anderson Cancer Center	Riddell, Stanley; Engelhard, Victor
RP160188pe/ RP160188	Schluns, Kimberly	The University of Texas M. D. Anderson Cancer Center	Engelhard, Victor
RP160482pe/ RP160482	Heimberger, Amy	The University of Texas M. D. Anderson Cancer Center	Engelhard, Victor
RP160577pe/ RP160577	Poojary, Venuprasad	Baylor Research Institute	Cooney, Kathleen
RP160497pe/ RP160497	Krishnan, Sunil	The University of Texas M. D. Anderson Cancer Center	Berbeco, Ross
RP160589	Chapkin, Robert	Texas AgriLife Research	Fearon, Eric; Greene, Geoffrey

Application ID	Applicant	Institution	Conflict Noted
RP160015	Ness, Roberta	The University of Texas	Haiman, Christopher;
KI 100013	rvess, reoteria	Health Science Center at	Kushi, Lawrence
		Houston	Rushi, Lawrence
RP160030	Gerber, David	The University of Texas	Barlow, William
KI 100050	Gerber, Buvia	Southwestern Medical	Darrow, william
		Center	
RP160097	Spitz, Margaret	Baylor College of	Martinez, Maria
100077	Spitz, margaret	Medicine	, wara
RP160145	Bast, Robert	The University of Texas	Kushi, Lawrence; Li,
	,	MD Anderson Cancer	Christopher
		Center	P
Applications	Not Recommended for	PIC or Oversight Commi	ttee Consideration
RP160117pe/	Chen, Benjamin	The University of Texas	Bart Williams
RP160117*	Chen, Benjamin	Southwestern Medical	Dart Williams
111 100117		Center	
RP160472pe	Cox, Marc	The University of Texas	McMahon, Martin
r ·	,	at El Paso	,
RP160079pe	Saikumar, Pothana	The University of Texas	Sonenberg, Nahum
•	ŕ	Health Science Center at	J.
		San Antonio	
RP160113pe	Davis, Anthony	The University of Texas	Tomkinson, Alan;
		Southwestern Medical	Chazin, Walter
		Center	
RP160304pe	Denicourt, Catherine	The University of Texas	Petrini, John
		Health Science Center at	
		Houston	
RP160335pe/	Wang, Bin	The University of Texas	Matthew Weitzman
RP160335*		M. D. Anderson Cancer	
DD4 (02=1	D 4 D 11	Center	TD 1: A1
RP160374pe	Boothman, David	The University of Texas	Tomkinson, Alan
		Southwestern Medical	
DD1/0/11mg	Schiff, Rachel	Center Paylor Callaga of	Datrini John
RP160611pe	Schiff, Rachel	Baylor College of Medicine	Petrini, John
RP160621pe	Latham, Michael	Texas Tech University	Petrini, John
RP160506pe	Aiden, Erez	Baylor College of	Bernstein, Bradley;
111 100300рс	1114011, 12102	Medicine Medicine	Hahn, William
RP160537pe	Kim, Min	The Methodist Hospital	Wahl, Geoffrey
111 1000 / pc		Research Institute	, Storing
RP160477pe	Hassan, Manal	The University of Texas	Petersen, Gloria;
P		M. D. Anderson Cancer	Martinez, Maria
		Center	
	I.	1	1

Application ID	Applicant	Institution	Conflict Noted
RP160076pe	Jha, Mithilesh	The University of Texas Health Science Center at San Antonio	Hochster, Howard
RP160143pe/ RP160143	Nurieva, Roza	The University of Texas M. D. Anderson Cancer Center	Stadler, Walter; Engelhard, Victor
RP160176pe/ RP160176*	Sharma, Padmanee	The University of Texas M. D. Anderson Cancer Center	Riddell, Stanley
RP160230pe	Trippier, Paul	Texas Tech University Health Sciences Center	Balk, Steven
RP160336pe/ RP160336*	Diab, Adi	The University of Texas M. D. Anderson Cancer Center	Engelhard, Victor
RP160359pe	Bhattacharya, Pratip	The University of Texas M. D. Anderson Cancer Center	Haas-Kogan, Daphne
RP160580pe	Biros, George	The University of Texas at Austin	Mitchell, Duane
RP160645pe/ RP160645*	Jo, Javier	Texas Engineering Experiment Station	Liu, Jonathan; Sutcliffe, Julie
RP160648pe/ RP160648*	Chen, Wei	The University of Texas at Arlington	Zinn, Kurt
RP160222	Rao, Hai	The University of Texas Helath Science Center at San Antonio	Carol Prives
RP160373	Naora, Honami	The University of Texas MD Anderson Cancer Center	Greene, Geoffrey
RP160395*	Lee, Min Gyu	The University of Texas MD Anderson Cancer Center	Belinksy, Steven
RP160535	Kang, Min	Texas Tech University Health Sciences Center	DeClerck, Yves
RP160567*	Zhang, Michael	The University of Texas at Dallas	Lowlor, Elizabeth
RP160168	Felini, Martha	University of North Texas Health Science Center at Fort Worth	Olshan, Andrew
RP160224	Schick, Vanessa	The University of Texas Health Science Center at Houston	Brandon, Thomas

Application ID	Applicant	Institution	Conflict Noted
RP160354*	Stingo, Francesco	The University of Texas MD Anderson Cancer Center	Barlow, William; Li, Christopher; Peterson, Gloria
RP160408*	Shen, Qiang	The University of Texas MD Anderson Cancer Center	Kumar, Nagi
RP160470	Valerio, Melissa	The University of Texas Health Science Center at Houston	Kushi, Lawrence
RP160499*	Minnix, Jennifer	The University of Texas MD Anderson Cancer Center	Brandon, Thomas; Schnoll, Robert
RP160527	Hanash, Samir	The University of Texas MD Anderson Cancer Center	Barlow, William; Li, Christopher; Mucci, Lorelei
RP160554	Bondy, Melissa	Baylor College of Medicine	Haiman, Christopher; Martinez, Maria
RP160587	Wetter, David	Rice University	Brandon, Thomas
RP160525*	Jiang, Ning	The University of Texas at Austin	Press, Oliver; Riddell, Stanley
RP160540	Reynolds, Charles	Texas Tech University Health Sciences Center	Grupp, Stephen; Kast, W. Martin;
RP160466	Yuan, Baohong	University of Texas at Arlington	Zinn, Kurt

De-Identified Overall Evaluation Scores

Individual Investigator Research Awards

Academic Research Cycle 16.1

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within the Individual Investigator Research Awards mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

This comprehensive list of Individual Investigator Research Awards de-identified application scores created for the purpose of this CEO affidavit packet combines the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not.

Also, see the "Final Overall Evaluation Scores and Rank Order Scores" section for an explanation of the Scientific Review Council's review and recommendation of grant awards.

Application ID	Overall Final Evaluation Score
RP160192*	1.3
RP160451*	1.5
RP160180*	1.8
RP160384*	1.9
RP160318*	2.0
RP160497*	2.0
RP160229*	2.0
RP160169*	2.1
RP160089*	2.1
RP160501*	2.1
RP160340*	2.2
RP160183*	2.2
RP160232*	2.2
RP160242*	2.3
RP160440*	2.3
RP160013*	2.3
RP160019*	2.3
RP160051*	2.3
RP160211*	2.4
RP160023*	2.4
RP160319*	2.4
RP160188*	2.4
RP160255*	2.5
RP160517*	2.5
RP160345*	2.5

^{* =} Recommended for funding

	Overall Final
Application ID	Evaluation Score
RP160307*	2.5
aa	2.5
RP160482*	2.6
RP160121*	2.6
ab	2.7
RP160268*	2.7
RP160512*	2.7
RP160577*	2.7
RP160617*	2.7
ac	2.8
RP160493*	2.8
ad	2.9
RP160054*	2.9
RP160235*	2.9
RP160150*	3.0
RP160471*	3.1
ae	3.1
af	3.1
RP160462*	3.2
RP160035*	3.2
ag	3.3
ah	3.3
ai	3.3
aj	3.3
ak	3.3
al	3.3
am	3.3
an	3.3
ao	3.3
ар	3.3
aq	3.4
ar	3.4
as	3.4
at	3.6
au	3.7
av	3.7
ax	3.7
ay	3.7
az	3.7
ba	3.7
bb	3.7
bc	3.7
bd	3.7
be	3.8
~~	5.0

Application ID	Overall Final
	Evaluation Score
bf	3.8
bg	3.8
bh	3.8
bi	3.9
bj	4.0
bk	4.0
bl	4.0
bm	4.0
bn	4.0
bo	4.0
bp	4.0
bq	4.0
br	4.0
bs	4.0
bt	4.0
bu	4.0
bv	4.0
bw	4.0
bx	4.0
by	4.0
bz	4.2
ca	4.2
cb	4.3
СС	4.3
cd	4.3
ce	4.3
cf	4.3
cg	4.3
ch	4.3
ci	4.3
cj	4.3
ck	4.3
cl	4.4
cm	4.4
cn	4.4
СО	4.5
ср	4.5
cq	4.6
cr	4.6
CS	4.7
ct	4.7
cu	4.7
CV	4.7
CW	4.7

Application ID	Overall Final
	Evaluation Score
СХ	4.7
су	4.7
CZ	4.7
da	4.8
db	4.9
dc	5.0
dd	5.0
de	5.0
df	5.0
dg	5.0
dh	5.0
di	5.0
dj	5.0
dk	5.0
dl	5.3
dm	5.3
dn	5.3
do	5.3
dp	5.6
dq	5.7
dr	5.7
ds	5.7

Individual Investigator Research Awards

Final Scores for Preliminary Evaluations

Academic Research Cycle 16.1

The final overall score of a grant application that does not move forward to full review is the average of the preliminary evaluation scores received by the primary reviewers.

Application ID	Final Overall
	Evaluation Score
Ka	3.0
Kb	3.3
kc	3.3
Kd	3.3
Ke	3.3
Kf	3.3
Kg	3.3
Kh	3.3
Ki	3.3
Kj	3.3
Kk	3.3
KI	3.3
Km	3.3
Kn	3.3
Ко	3.3
Кр	3.3
Kq	3.3
Kr	3.3
Ks	3.3
Kt	3.3
Ku	3.3
Kv	3.3
Kw	3.3
Kx	3.3
Ку	3.3
Kz	3.3
La	3.3
Lb	3.3
Lc	3.3
Ld	3.7
Le	3.7
Lf	3.7
Lg	3.7
Lh	3.7
Li	3.7
Lj	3.7

Application ID	Final Overall
	Evaluation Score
Lk	3.7
Ll	3.7
Lm	3.7
Ln	3.7
Lo	3.7
Lp	3.7
Lq	3.7
Lr	3.7
Ls	3.7
Lt	3.7
Lu	3.7
Lv	3.7
Lw	3.7
Lx	3.7
Ly	3.7
Lz	3.7
Ma	3.7
Mb	3.7
Mc	3.7
Md	3.7
Me	3.7
Mf	3.7
Mg	3.7
Mh	3.7
Mi	3.7
Mj	3.7
Mk	3.7
MI	3.7
Mm	3.7
Mn	3.7
Mo	3.7
Mp	3.7
Mq	3.7
Mr	3.7
Ms	3.7
Mt	3.7
Mu	3.7
Mv	4.0
Mw	4.0
Mx	4.0
Му	4.0
Mz	4.0
Na	4.0
Nb	4.0

Application ID	Final Overall
	Evaluation Score
Nc	4.0
Nd	4.0
Ne	4.0
Nf	4.0
Ng	4.0
Nh	4.0
Ni	4.0
Nj	4.0
Nk	4.0
NI	4.0
Nm	4.0
Nn	4.0
No	4.0
Np	4.0
Nq	4.0
Nr	4.0
Ns	4.0
Nt	4.0
Nu	4.0
Nv	4.0
Nw	4.0
Nx	4.0
Ny	4.0
Nz	4.3
Oa	4.3
Ob	4.3
Oc	4.3
Od	4.3
Oe	4.3
Of	4.3
Og	4.3
Oh	4.3
Oi	4.3
Oj	4.3
Ok	4.3
Ol	4.3
Om	4.3
On	4.3
00	4.3
Ор	4.3
Oq	4.3
Or	4.3
Os	4.3
Ot	4.3
<u> </u>	7.3

Application ID	Final Overall
	Evaluation Score
Ou	4.3
Ov	4.3
Ow	4.3
Ox	4.3
Оу	4.3
Oz	4.3
Pa	4.3
Pb	4.3
Pc	4.3
Pd	4.3
Pe	4.3
Pf	4.3
Pg	4.3
Ph	4.3
Pi	4.3
Pj	4.3
Pk	4.3
Pl	4.3
Pm	4.5
Pn	4.7
Ро	4.7
Рр	4.7
Pq	4.7
Pr	4.7
Ps	4.7
Pt	4.7
Pu	4.7
Pv	4.7
Pw	4.7
Px	4.7
Ру	4.7
Pz	4.7
Qa	4.7
Qb	4.7
Qc	4.7
Qd	4.7
Qe	4.7
Qf	4.7
Qg	4.7
Qh	4.7
Qi	5.0
Qj	5.0
Qk	5.0
Ql	5.0
~'	

A 10 44 45	
Application ID	Final Overall
	Evaluation Score
Qm	5.0
Qn	5.0
Qo	5.0
Qp	5.0
Qq	5.0
Qr	5.0
Qs	5.0
Qt	5.0
Qu	5.0
Qv	5.0
Qw	5.0
Qx	5.0
Qy	5.3
Qz	5.3
Ra	5.3
Rb	5.3
rc	5.3
Rd	5.3
Re	5.3
Rf	5.3
Rg	5.3
Rh	5.3
Ri	5.3
Rj	5.3
Rk	5.3
RI	5.7
Rm	5.7
Rn	5.7
Ro	5.7
Rp	5.7
Rq	5.7
Rr	5.7
Rs	6.0
Rt	6.0
Ru	6.0
Rv	6.3
Rw	6.3
Rx	6.3
Ry	6.3
Rz	6.3
Sa	6.7
Sb	6.7
SC	7.7

Final Overall Evaluation Scores and Rank Order Scores





Ludwig Institute for Cancer Research Ltd October 29, 2015

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Head, Laboratory of Cancer Genetics San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

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Mr. Pete Geren

Oversight Committee Presiding Officer Cancer Prevention and Research Institute of Texas Via email to pgcprit@sidrichardson.org

Mr. Wayne R. Roberts Chief Executive Officer Cancer Prevention and Research Institute of Texas Via email to wroberts@cprit.state.tx.us

Dear Mr. Geren and Mr. Roberts,

In reviewing the list of recommended applications, we were made aware of one minor error in scoring. Application RP160268 was assigned a score of 2.6 in the list, and the actual score should be 2.7. This recommended application was initially placed in row 41 and now appears in row 44. The change of score is reflected in the attached revised list. This does not change the outcome of the SRC recommendation.

Sincerely yours,

Richard D. Kolodner, Ph.D.

Chair, CPRIT Scientific Review Council





Ludwig Institute for Cancer Research Ltd October 29, 2015

Richard D. Kolodner Ph.D.

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Head, Laboratory of Cancer Genetics San Diego Branch

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Mr. Pete Geren Oversight Committee Presiding Officer Cancer Prevention and Research Institute of Texas Via email to pgcprit@sidrichardson.org

Mr. Wayne R. Roberts Chief Executive Officer Cancer Prevention and Research Institute of Texas Via email to wroberts@cprit.state.tx.us

Dear Mr. Geren and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for the Individual Investigator Research Awards (IIRA), Individual Investigator Research Awards for Computational Biology (IIRACB), Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA), Individual Investigator Research Awards for Prevention and Early Detection (IIRAP), Research Training Awards (RTA), and Research Training Awards - Renewal (RTA-R) grant mechanisms. The SRC met on Friday, October 23, 2015 to consider the applications recommended by the peer review panels following their meetings that were held September 29 - October 7, 2015. During the SRC discussion, it was determined that the success rates (percentage of the number recommended/number reviewed) for four panels were much higher than the rates for the other three panels and higher than the historical approval rates. It was suggested that these four panels reduce their success rates to fall in line with the other panels, and all chairs agreed to the scoring adjustments. This resulted in some applications not being recommended for grant awards that received scores equal to or more favorable than some applications that were recommended for grant awards. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded after adjustments were made based on success rates.

Recommended funding amounts and the overall evaluation score are stated for each grant application. The SRC accepted the recommendations of the peer review panels concerning adjustments to three grant applications. These adjustments with justifications are listed at the end of the list of recommended projects. The total amount for the applications recommended is \$62,761,270.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.





Sincerely yours,

Richard D. Kolodner, Ph.D.

Chair, CPRIT Scientific Review Council

Attachment

Rank	App ID	Organization/Company	Application Title	Award Amount	Mech.	Overall Score
Kank	App ID	* *		Amount		Score
	DD1 (0157	The University of Texas	Cancer Intervention and Prevention	Ф2 002 250	RTA-	1.0
1	RP160157	Southwestern Medical Center	Discoveries Program	\$3,993,250	Renewal	1.2
			Decoding Cellular Heterogeneity of			
2	RP160192	Baylor College of Medicine	Malignant Glioma	\$899,701	IIRA	1.3
			Protein Truncation Mutations in WIP1:			
3	RP160451	Baylor College of Medicine	Effects on Cancer and Hematopoiesis	\$900,000	IIRA	1.5
			Development of Therapeutics			
			Targeting Truncated Adenomatous			
			Polyposis Coli (APC) as a Novel			
		The University of Texas	Prevention and Intervention Strategy			
4	RP160180	Southwestern Medical Center	for Colorectal Cancer	\$900,000	IIRA	1.8
			A novel epigenetic reader as			
		The University of Texas M. D.	therapeutic target in MLL-translocated		IIRACC	
5*	RP160237	Anderson Cancer Center	pediatric leukemias	\$900,000	A	1.8
			Baylor College of Medicine			
			Comprehensive Cancer Training		RTA-	
6	RP160283	Baylor College of Medicine	Program	\$3,986,268	Renewal	1.9
		The University of Texas				
_		Health Science Center at San			IIRACC	
7	RP160487	Antonio	Cytokine signaling in Ewing sarcoma	\$1,200,000	A	1.9
			A Randomized Controlled Trial (RCT)			
			of Patient Navigation for Lung Cancer			
	DD1 60000	The University of Texas	Screening in an Urban Safety-Net	01.402 51 5	110 : 5	
8	RP160030	Southwestern Medical Center	System	\$1,492,616	IIRAP	1.9
			Promoting The Functions of Memory T			
9	RP160384	Baylor College of Medicine	cells for Adoptive T cell Therapy	\$887,676	IIRA	1.9
			Role of Long Non-Coding RNAs in			
			Breast Cancer: Identification,			
		The University of Texas	Characterization, and Determination of			
10	RP160318	Southwestern Medical Center	Molecular Functions	\$886,652	IIRA	2.0

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			Arylhydrocarbon receptor mediated			
11	RP160589	Texas AgriLife Research	modulation of colorectal cancer by microbiota metabolites	\$890,840	IIRAP	2.0
11	KI 100389	Texas Agrillic Research	Pediatric Radiation Oncology with	\$670,640	ШХЛ	2.0
		The University of Texas	Movie Induced Sedation Effect		IIRACC	
12**	RP160190	Southwestern Medical Center	(PROMISE)	\$900,000	A	2.0
		The University of Texas M. D.	Amplified gold nanoparticle-mediated			
13	RP160497	Anderson Cancer Center	radiosensitization of tumors	\$899,309	IIRA	2.0
			Imaging-based quantitative analysis of			
			vascular perfusion and tissue			
	DD4 60000	The University of Texas M. D.	oxygenation to improve therapy of	#00 .		• 0
14	RP160229	Anderson Cancer Center	hepatocellular carcinoma	\$885,901	IIRA	2.0
		The Heimeritan of Terror	Molecular Mechanism of NLRP12-			
15	RP160169	The University of Texas Southwestern Medical Center	mediated Regulation of Colorectal Cancer	\$897,707	IIRA	2.1
13	11110107		DIS3L2 in Childhood Wilms Tumor:	φυ//,/0/	IIRACC	4,1
16***	RP160249	The University of Texas Southwestern Medical Center	Mechanism to Medicines	\$1,200,000	A A	2.1
10	KI 100249	Southwestern Medical Center	Carbamoyl Phosphate Synthase-1: A	\$1,200,000	A	2.1
		The University of Texas	new metabolic liability in non-small			
17	RP160089	Southwestern Medical Center	cell lung cancers	\$900,000	IIRA	2.1
		The Methodist Hospital	De-Orphanizing TLX: Implications for	. ,		
18	RP160501	Research Institute	Glioblastomas	\$878,969	IIRA	2.1
		The University of Texas		. ,		
19	RP160622	Southwestern Medical Center	Computational live cell histology	\$392,779	IIRACB	2.1
			Cancer Prevention Post-Graduate	4 9		
			Training Program in Integrative			
20	RP160097	Baylor College of Medicine	Epidemiology	\$2,986,890	RTA	2.1
		The University of Texas	Collaborative Training of a New Cadre			
2.1	DD1 60015	Health Science Center at	of Innovative Cancer Prevention	# 4 000 000	RTA-	2.1
21	RP160015	Houston	Researchers	\$4,000,000	Renewal	2.1
	DD4 600 40	The University of Texas	The role of the Lats kinases in	#000 # 00		
22	RP160340	Southwestern Medical Center	sarcomatoid renal cell carcinoma	\$899,598	IIRA	2.2
			Exploiting molecular and metabolic			
	DD1 (0105	The University of Texas M. D.	dependencies to optimize personalized	# 0000000	115	
23	RP160183	Anderson Cancer Center	therapeutic approaches for melanomas	\$900,000	IIRA	2.2
			Understanding Biological and Physical			
		The University of Texas M. D.	Factors Affecting Response to Proton Therapy to Improve its Clinical			
24	RP160232	Anderson Cancer Center	Effectiveness	\$879,362	IIRA	2.2
	12130252		Role of Cohesin in Hematopoiesis and	\$0.7,502		
			Myeloid Leukemia in Children with		IIRACC	
25	RP160022	Baylor College of Medicine	Down Syndrome	\$1,905,638	A	2.2
		The University of Texas M. D.	Mechanisms and targeting strategies for			
26	RP160242	Anderson Cancer Center	SWI/SNF mutations in cancer	\$900,000	IIRA	2.3
			Targeting the undruggable: a first-in-			
		The University of Texas	class inhibitor of the HIF-2			
27	RP160440	Southwestern Medical Center	transcription factor	\$899,412	IIRA	2.3

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28	RP160145	The University of Texas M. D. Anderson Cancer Center	Early Detection of Ovarian Cancer with Tumor Associated Proteins and Autoantibodies	\$1,497,595	IIRAP	2.3
29	RP160013	The University of Texas M. D. Anderson Cancer Center	Visualizing T-cell trafficking	\$900,000	IIRA	2.3
30	RP160019	The University of Texas M. D. Anderson Cancer Center	An Adaptive Personalized Clinical Trial using a Patient-Derived Xenograft Strategy to Overcome Ibrutinib Resistance in Mantle Cell Lymphoma	\$841,606	IIRA	2.3
31	RP160051	Texas A&M University System Health Science Center	Improving contrast for antibody-based tumor detection using PET	\$887,134	IIRA	2.3
32	RP160023	The University of Texas M. D. Anderson Cancer Center	Investigating the genetic and molecular mechanisms underlying RAS/ERK substrate network Novel tumorigenic mechanisms of the	\$900,000	IIRA	2.4
33	RP160211	The University of Texas Southwestern Medical Center	LKB1 tumor suppressor in endometrial and cervical cancer	\$896,653	IIRA	2.4
34	RP160319	The University of Texas Southwestern Medical Center	Role of PARP-1 in Estrogen Receptor Enhancer Function and Gene Regulation Outcomes in Breast Cancers	\$884,315	IIRA	2.4
35	RP160124	The University of Texas Health Science Center at San Antonio	Chemoprevention of Colon Cancer by Anti-inflammatory Blockade Using Neem	\$899,617	IIRAP	2.4
36	RP160188	The University of Texas M. D. Anderson Cancer Center	Regulation of infiltration and function of tumor-resident CD8 T cells by IL-15	\$828,060	IIRA	2.4
37	RP160255	The University of Texas Southwestern Medical Center	Structural and Functional Analyses of the Spindle Checkpoint	\$900,000	IIRA	2.5
38	RP160307	The University of Texas Southwestern Medical Center	Targeting Metastatic Pathways	\$900,000	IIRA	2.5
39	RP160517	The University of Texas M. D. Anderson Cancer Center	Exosomal DNA as a surrogate biomarker for early diagnosis and therapeutic stratification in pancreatic cancer	\$891,938	IIRA	2.5
40	RP160345	Baylor College of Medicine	Engineering T cells to ensure specificity for tumor cells and their environment	\$900,000	IIRA	2.5
41	RP160482	The University of Texas M. D. Anderson Cancer Center	Nanoparticle Targeted STAT3 Immune Expression Clinical Safety and Efficacy of Third	\$888,429	IIRA	2.6
42	RP160121	The University of Texas M. D. Anderson Cancer Center	party, fucosylated, cord blood derived regulatory T cells to prevent graft versus host disease	\$900,000	IIRA	2.6
43	RP160520	The University of Texas Southwestern Medical Center	Effect of Chest Radiation Therapy on Cardiomyocyte Turnover	\$897,570	IIRAP	2.6
44	RP160268	The University of Texas Southwestern Medical Center	DNA damage-induced small non- coding RNAs: mechanism and their role in cancer development	\$900,000	IIRA	2.7

LUDWIG CANCER RESEARCH

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			Integrin-mediated IL-18 signaling in			
		The University of Texas	the prevention and treatment of			
		Health Science Center at San	inflammation-associated colorectal			
45	RP160512	Antonio	cancer	\$859,620	IIRA	2.7
			A novel function of Itch in controlling			
			IL-17-induced inflammation in colon			
46	RP160577	Baylor Research Institute	cancer	\$900,000	IIRA	2.7
			Optimizing therapeutic strategies			
		The University of Texas at	against lung cancer using Multi-			
47	RP160617	Dallas	Modality Imaging	\$899,999	IIRA	2.7
			Characterization and pharmacological			
		The University of Texas	targeting of the oncogenic activity of			
48	RP160493	Southwestern Medical Center	Jumonji enzymes	\$899,997	IIRA	2.8
			The CTC Circulator Phenotype:	Í		
			Insights into Mechanisms of Breast			
49	RP160054	Baylor College of Medicine	Cancer Dormancy	\$884,332	IIRA	2.9
49	KF 100034	The University of Texas	Regulation of tumor aggressiveness and	\$664,332	IINA	2.9
		Health Science Center at	immune suppression in lung			
50	DD160225		adenocarcinoma	000 000	IID A	2.0
50	RP160235	Houston	ı	\$900,000	IIRA	2.9
			Radiogenomic Screen to Identify Novel			
			Proliferation-associated Glioblastoma			
			Genomic Therapeutic Targets:			
5.1	DD1 601 50	The University of Texas M. D.	Discovery and Mechanistic Validation	#00 7.637	IID 4	2.0
51	RP160150	Anderson Cancer Center	Study	\$897,627	IIRA	3.0
			High resolution imaging for early and			
52	RP160460	Rice University	better detection of bladder cancer	\$873,765	IIRAP	3.0
		The University of Texas M. D.	Identifying new epigenetic	·		
53	RP160471	Anderson Cancer Center	vulnerabilities in pancreatic cancer	\$900,000	IIRA	3.1
- 55	10 100 1/1	- Indiana Canton Conton	Systematic identification of small	Ψ>00,000	11141	5.1
			molecule inhibitors that manipulate			
54	RP160462	Baylor College of Medicine	telomerase activities	\$898,288	IIRA	3.2
JT	100402	Buylor Conege of Wicdichie	The role of Prdm16 and histone H3	\$676,266	шил	J.L
			lysine 9 methyltransferase complex in			
55	RP160035	Baylor College of Medicine	MDS	\$872,157	IIRA	3.2
33	KI 100033	Daylor College of Medicille	MIDS	\$6/4,13/	ШХА	3.4

^{*}RP160237 - The peer review panel recommended reducing the budget to \$300,000 per year for 3 years for a total of \$900,000 based on the scope and depth of the work proposed.

^{**}RP160190 - The peer review panel recommended not funding Aim 4 (Pilot prospective clinical trial) and reducing the budget to \$300,000 per year for 3 years for a total of \$900,000. The final score was based on revised scope with full deletion of Aim 4.

^{***}RP160249 - The peer review panel recommended that given the absence of a clinical trial, the budget should be reduced to \$300,000 per year for 4 years for a total of \$1,200,000.





Success Rate by Panel				
Peer Review	Success	Score		
Panel	Rate	Cutoff		
BCR1	10%	2.3		
BCR2	11%	3.2		
СВ	9%	3.2		
CPR	9%	2.4		
CTCR/TCR	13%	2.7		
ITI	11%	3.0		

Success Rate by Mechanism vs. Total Reviewed				
Mechanism	Success Rate	# Recommended		
IIRA	11%	39/347		
IIRACB	2%	1/50		
IIRACCA	11%	5/44		
IIRAP	13%	6/44		
RTA	14%	1/7		
RTA-R	50%	3/6		
Overall	11%	55/498		

Percent of Applications Recommended by				
Mechanism vs. Total Recommended				
Mechanism	Mechanism # Recommended Percentage			
IIRA	39/55	71%		
IIRACB	1/55	2%		
IIRACCA	5/55	9%		
IIRAP	6/55	11%		
RTA	1/55	2%		
RTA-R	3/55	5%		
Overall	55/55	100%		



CEO Affidavit Supporting Information

FY 2016—Cycle 1
Individual Investigator Research Awards
for Computational Biology

Request for Applications



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS RFA R-16-IIRACB-1

Individual Investigator Research Awards for Computational Biology

Please also refer to the Instructions for Applicants document, which will be posted on March 20, 2015

Application Receipt Opening Date: March 20, 2015 **Application Receipt Closing Date:** May 20, 2015

FY 2016

Fiscal Year Award Period September 1, 2015-August 31, 2016

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RFA VERSION HISTORY

Rev 02/20/15 RFA release

1. ABOUT CPRIT

The state of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the
 potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the state of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The principles and priorities of the Scientific Research program will guide CPRIT staff, peer reviewers, and the Scientific Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs. The program priorities for research adopted by the Oversight Committee include funding projects that address:

- A broad range of innovative, investigator-initiated research projects;
- Prevention and early detection;
- Rare and intractable cancers, including childhood cancers;
- Cancers of importance in Texas;
- Computational biology and analytic methods; and
- Building Infrastructure.

2. RATIONALE

Cancer is a complex disease involving multiple genetic alterations that result in modifications of a large number of cellular processes, both within the cancer cell and in surrounding host tissues. Descriptions of morphological and physiological alterations in cancers using imaging technologies have generated enormous quantities of data, as have analyses of the changes in

cancer cells at the molecular and pathway levels. New methods from computational biology for cataloging and analyzing such data may accelerate the ability to define cancer prognosis and patient management.

Additionally, it is becoming quite clear that the approach of inhibiting one altered gene or pathway will not be curative for most cancers. Because cancer cell behavior is governed by multiple, nonlinear, interacting pathways, a systems approach is needed. Mathematical models that describe the behavior of cancer cells might be used to predict their responses to combinations and/or sequences of targeted therapies. The use of such computational models could accelerate progress in drug development and patient selection for various treatments.

Other work across the spectrum of computational biology may address a wide array of problems and challenges in cancer research, including statistical (data analysis), dimensional (visualization and multiscale modeling), and semantic (natural language) research topics.

3. RESEARCH OBJECTIVES

This Request for Applications (RFA) solicits applications for innovative mathematical or computational research projects addressing questions that will advance current knowledge in any aspect of cancer. Applications may address any topic or issue related to cancer causation, identification of populations at risk, prevention, early progression, early detection, treatment, or outcomes. For example, research may address data analysis of cellular pathways, microarrays, cellular imaging, cancer imaging, or genomic, proteomic, and metabolomic databases. It may address descriptive mathematical models of cancer, as well as mechanistic models of cellular processes and interactions. Finally, it may also use artificial intelligence approaches to build new tools for mining cancer research and treatment databases. Partnering of computational scientists with cancer biologists or oncologists is highly recommended; a truly interdisciplinary team that addresses models that could become simulations of structure or pathway functional relationships and changes of these relationships over the disease progression is highly recommended. CPRIT expects the outcomes of activities supported by this mechanism to lead to new insights into cancer biology or clinical outcomes in the long term. CPRIT encourages applications that seek to apply or develop state-of-the-art technologies, tools, and/or resources. Successful applicants should be working in a research environment capable of supporting potentially high-impact studies in computational biology, biostatistics, and/or mathematics.

The subject of applications may include, but is not limited to, the following:

- Innovative analyses of various cancer-related databases
- Computational systems biology approaches to cancer drug development
- Identification of subjects at risk of developing cancer
- Image analysis of cells, tissues, organs, and human subjects
- In silico models of cancer development
- New methodologies for design of clinical trials
- Modeling of cancer outcomes and economics
- Models of cancer cell signaling systems
- Modeling the impact of combinations and sequences of targeted therapy applied to cancer cells

The *degree of relevance* to reducing the burden of cancer will be an important criterion for evaluation of projects for funding by CPRIT.

4. FUNDING INFORMATION

Applicants may request a maximum of \$150,000 in total costs per year for up to 3 years. Exceptions to these limits may be requested if extremely well justified (see section 8.2.9). Applications funded in this cycle will be eligible for competitive renewal. Funds may be used for salary and fringe benefits, research supplies, equipment, and travel to scientific/technical meetings or collaborating institutions. Requests for funds to support construction and/or renovation will not be approved under this funding mechanism. State law limits the amount of award funding that may be spent on indirect costs to no more than 5% of the total award amount.

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization that conducts research is eligible to apply for funding under this award mechanism.
 A public or private company is not eligible for funding under this award mechanism; these entities must use the appropriate award mechanism(s) under CPRIT's Product Development Program.
- The Principal Investigator (PI) must have a doctoral degree, including MD, PhD, DDS,
 DMD, DrPH, DO, DVM, or equivalent, and must reside in Texas during the time the research that is the subject of the grant is conducted.

- A PI may submit only 1 new application under this RFA during this funding cycle. A PI may not submit applications to this RFA and to RFA-R-16-IIRA-1 or RFA R-16-IIRACCA-1 or RFA-R-16-IIRAP. Only 1 IIRACB application per cycle is allowed. An investigator who is the PI on 3 or more CPRIT grants of any type that will be active December 1, 2015 is not eligible to submit an application in response to this RFA.
- Applications that address untargeted research, Prevention and Early Detection, or Cancers in Children and Adolescents should be submitted under the appropriate targeted RFA.
- Because this award mechanism is intended to support research directed by a single investigator, only 1 Co-PI may be included. Collaborators should have specific and welldefined roles.
- Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the state of Texas, but non—Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PI, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the PI, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds, or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

• CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. RESUBMISSION POLICY

Because Individual Investigator Research Awards for Computational Biology for Cancer is a new award mechanism, resubmission in not available under this RFA. If a previously unfunded IIRA application is responsive to the IIRACB RFA, it may be submitted as a new application under the IIRACB mechanism.

7. RENEWAL POLICY

An application originally funded by CPRIT as an IIRA that is appropriate for the IIRACB mechanism may be submitted under this RFA for a competitive renewal. See <u>section 8.2.5</u>. Competitive renewals are not subject to preliminary evaluation. Renewal applications move directly to the full peer review phase. See <u>section 9.2</u>.

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and submit an application. The Co-PI, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (ASO) (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on March 20, 2015, and must be submitted by 3 PM

central time on May 20, 2015. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

8.1.1. Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via email to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in <u>section 5</u> will be administratively withdrawn without review.

8.2.1. Abstract and Significance (5,000 characters)

Clearly explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the Research Plan. Clearly address how the proposed project, if successful, will have a major impact on cancer. Summarize how the proposed research creates new paradigms or challenges existing ones. Indicate whether this research plan represents a new direction for the PI.

Note: It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance statement alone. Therefore, applicants are advised to prepare this section wisely. Applicants should not waste this valuable space by stating obvious facts (eg, that cancer is a significant problem; that better diagnostic and therapeutic approaches are needed urgently; or that the type of cancer of interest to the PI is important, vexing, or deadly). Based on this statement (and the Budget and Justification and Biographical Sketches), applications that are judged to offer only modest contributions to the field of cancer research or that do not sufficiently capture the reviewers' interest may be excluded from further peer review (see section 9.1).

8.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer research, early diagnosis, prevention, or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Do not include any proprietary information in the Layperson's Summary. The Layperson's Summary will also be used by advocate reviewers (section 9.2) in evaluating the significance and impact of the proposed work.

8.2.3. Goals and Objectives

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success.

8.2.4. Timeline (1 page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.5. Renewal Summary (2 pages)

Applicants preparing a renewal must describe and demonstrate that appropriate/adequate progress has been made on the current funded award to warrant further funding. Publications and manuscripts in press that have resulted from work performed during the initial funded period should be listed in the renewal summary.

8.2.6. Research Plan (10 pages)

Background: Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed.

Hypothesis and Specific Aims: Concisely state the hypothesis and/or specific aims to be tested or addressed by the research described in the application.

Research Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data that support the proposed hypothesis are encouraged but not required.

8.2.7. Vertebrate Animals and/or Human Subjects (1 page)

If vertebrate animals will be used, provide an outline of the appropriate protocols that will be followed. If human subjects or human biological samples will be used, provide a plan for recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism.

8.2.8. Publications/References

Provide a concise and relevant list of publications/references cited for the application.

8.2.9. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. Do not exceed \$150,000 per year over a maximum period of 3 years. Applicants are advised not to interpret the maximum allowable time and funding under this award as a suggestion that they should expand their anticipated work and budget to this level. Reasonable budgets clearly work in favor of the applicant.

However, if there is a highly specific and defensible need to request more than the maximum amount in any year(s) of the proposed budget, include a special and clearly labeled section in the budget justification that explains the request. Poorly justified requests of this type will likely have a negative impact on the overall evaluation of the application.

In preparing the requested budget, applicants should be aware of the following:

- Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. So-called grants management and facilities fees (eg, sponsored programs fees; grants and contracts fees; electricity, gas, and water; custodial fees;

- maintenance fees) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.
- The annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2016 is \$200,000; CPRIT FY 2016 is from September 1, 2015, through August 31, 2016. Salary does not include fringe benefits and/or facilities and administrative (F&A) costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

8.2.10. Biographical Sketches (2 pages each)

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. A biographical sketch must be provided for the PI and, if applicable, the Co-PI (as required by the online application receipt system). Up to 2 additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed 2 pages.

8.2.11. Current and Pending Support

Describe the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title, a 2-line summary of the goal of the project and, if relevant, a statement of overlap with the current application. At a minimum, current and pending support of the PI and, if applicable, the Co-PI must be provided.

8.2.12. Institutional/Collaborator Support and/or Other Certification (4 pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 4 pages may be provided.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively rejected without review.

9. APPLICATION REVIEW

9.1. Preliminary Evaluation

To ensure the timely and thorough review of only the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, all eligible applications may be preliminarily evaluated by CPRIT Scientific Research Program panel members for scientific merit and impact.

This preliminary evaluation will be based on a subset of material presented in the application—namely Abstract and Significance, Budget and Justification, and Biographical Sketches. Applications that do not sufficiently capture the reviewers' interest at this stage will not be considered for further review. Such applications will have been judged to offer only modest contributions to the field of cancer research and will be excluded from further peer review.

The applicant will be notified of the decision to disapprove the application after the preliminary evaluation stage has concluded. Due to the volume of applications to be reviewed, comments made by reviewers at the preliminary evaluation stage may not be provided to applicants. The preliminary evaluation process will be used only when the number of applications exceeds the capacity of the review panels to conduct a full peer review of all received applications.

9.2. Full Peer Review

Applications that pass preliminary evaluation will undergo further review using a 2-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts as well as advocate reviewers using the criteria listed below. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by Scientific Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC.

The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

9.3. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Peer Review Panel members and Scientific Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: An Oversight Committee Member, a PIC Member, a Scientific Review Panel member, or a Scientific Review Council member. Applicants should note that the CPRIT Program Integration Committee comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services.

The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted.

Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

Review Criteria 9.4.

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.

9.4.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study. Primary criteria include the following:

Significance and Impact: Will the results of this research, if successful, significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for patients? Is the application innovative? Does the applicant propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important underexplored or unexplored areas? If the research project is successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? Projects that modestly extend current lines of research will not be considered for this award. Projects that represent straightforward extensions of ongoing work, especially work traditionally funded by other mechanisms, will not be competitive.

Research Plan: Is the proposed work presented as a self-contained research project? Does the proposed research have a clearly defined hypothesis or goal that is supported by sufficient preliminary data and/or scientific rationale? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed?

Applicant Investigator: Does the applicant investigator demonstrate the required experience and creativity to make a significant contribution to the research? Does the applicant investigator demonstrate the required expertise to make a significant contribution in both mathematics and oncology, or are there appropriate collaborators or consultants with expertise in oncology or cancer biology? It is highly encouraged that applicant investigators engage such collaborators.

Applicants' credentials will be evaluated in a career stage—specific fashion. Have early career—

stage investigators received excellent training, and do their accomplishments to date offer great

promise for a successful career? Has the applicant devoted a sufficient amount of his or her time

(percentage effort) to this project?

Relevance: Does the proposed research address a significant problem related to cancer? Is it

likely to make an impact on this disease? This will be an important criterion for evaluation of

projects for CPRIT support.

9.4.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these

criteria potentially question the feasibility of the proposed research.

Secondary criteria include the following:

Research Environment: Does the research team have the needed expertise, facilities, and

resources to accomplish all aspects of the proposed research? Are the levels of effort of the key

personnel appropriate? Is there evidence of institutional support of the research team and the

project?

Vertebrate Animals and/or Human Subjects: If vertebrate animals and/or human subjects are

included in the proposed research, certification of approval by the institutional IACUC and/or

IRB, as appropriate, will be required before funding can occur.

Budget: Is the budget appropriate for the proposed work?

Duration: Is the stated duration appropriate for the proposed work?

10. KEY DATES

RFA

RFA release

February 20, 2015

Application

Online application opens

March 20, 2015, 7 AM central time

Application due

May 20, 2015, 3 PM central time

Application review

September - October 2015

Award

Award notification

November 2015

Anticipated start date

March 2016

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. Applicants are advised to review CPRIT's administrative rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed, and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements regarding demonstration of available funding.

13. CONTACT INFORMATION

13.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding scientific aspects of applications.

Dates of operation: February 20 – May 20, 2015 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time

Wednesday, 8 AM to 4 PM central time

Tel: 866-941-7146

Email: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Senior Manager for Research.

Tel: 512-305-8491

Email: Help@CPRITGrants.org

Website: <u>www.cprit.state.tx.us</u>

Third Party Observer Reports



CPRIT Research Peer Review Observation Report

Report #2015-09-29-RES

Program Name: Academic Research

Panel Name: FY16.1 Clinical & Translational Cancer

Research and Translational Cancer Research

Panel Date: September 29, 2015 Report Date: October 7, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Clinical & Translational Cancer Research and Translational Cancer Research peer review of applications for FY16 funding. The meeting was co-chaired by Richard O'Reilly and Margaret Tempero and held at the Marriott Suites Medical/Market Center in Dallas TX on September 29, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Clinical & Translational Cancer Research and Translational Cancer Research panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and co-chaired by Richard O'Reilly and Margaret Tempero on September 29, 2015.

The independent observer noted the following during our observation:

- Twenty-four applications were discussed within the Research Peer Review Meeting to determine which
 grants would receive CPRIT funding.
- Twenty-six peer review panelists, three advocate reviewers, three CPRIT staff members and five SRA employees were present for the meeting.
 - o Two of the twenty-six peer review panelists participated via teleconference.
- Thirteen conflicts of interest were identified prior to or during the meeting. Applications for nine
 conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest either
 left the room or did not participate telephonically and did not participate in the review of the conflicted
 application.
 - One of the nine conflicts did not sign out on the conflict of interest sign out sheet when leaving the room.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Research Peer Review Observation Report

Report #2015-09-30-RES

Program Name: Academic Research

Panel Name: FY16.1 Cancer Prevention Research

Panel Date: September 30, 2015 Report Date: October 7, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Cancer Prevention Research peer review of applications for FY16 funding. The meeting was chaired by Tom Sellers and held at the Marriott Suites Medical/Market Center in Dallas TX on September 30, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Cancer Prevention Research panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Tom Sellers on September 30, 2015.

The independent observer noted the following during our observation:

- Nineteen applications were discussed within the Research Peer Review Meeting to determine which
 grants would receive CPRIT funding.
- Seventeen peer review panelists, two advocate reviewers, four CPRIT staff members and five SRA
 employees were present for the meeting.
 - One of the seventeen peer review panelists participated via teleconference and for only one application.
- Twenty-one conflicts of interest were identified prior to or during the meeting. Applications for fifteen
 conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest either
 left the room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical
or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Research Peer Review Observation Report

Report #2015-10-01-RES

Program Name: Academic Research

Panel Name: FY16.1 Imaging Technology and

Informatics

Panel Date: October 1, 2015 Report Date: October 7, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Imaging Technology and Informatics peer review of applications for FY16 funding. The meeting was chaired by Sam Gambhir and held at the Marriott Suites Medical/Market Center in Dallas TX on October 1, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Imaging Technology and Informatics panel meeting held inperson. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Sam Gambhir on October 1, 2015.

The independent observer noted the following during our observation:

- Eighteen applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Twenty-one peer review panelists, two advocate reviewers, two CPRIT staff members and five SRA
 employees were present for the meeting.
 - One of the twenty-one peer review panelists participated via teleconference.
- Five conflicts of interest were identified prior to or during the meeting. Applications for two conflicts
 were discussed during the peer review panel. The reviewers with the conflicts of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Research Peer Review Observation Report

Report #2015-10-05-RES

Program Name: Academic Research

Panel Name: FY16.1 Basic Cancer Research 2

Panel Date: October 5, 2015 Report Date: October 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Basic Cancer Research 2 peer review of applications for FY16 funding. The meeting was chaired by Carol Prives and held at the Marriott Suites Medical/Market Center in Dallas TX on October 5, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Basic Cancer Research 2 panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Carol Prives on October 5, 2015.

The independent observer noted the following during our observation:

- Nineteen applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Fifteen peer review panelists, two advocate reviewers, two CPRIT staff members, five SRA employees
 and chair for the Scientific Review Council were present for the meeting.
 - o Two of the fifteen peer review panelists participated via teleconference.
 - One participated for review of only four applications and the other participated as an ad hoc reviewer for one application.
- Two conflicts of interest were identified prior to or during the meeting. Applications for one conflict
 was discussed during the peer review panel. The reviewer with the conflict of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
 - o The reviewer was present when final scores were still visible on projection screen.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Research Peer Review Observation Report

Report #2015-10-06-RES

Program Name: Academic Research

Panel Name: FY16.1 Basic Cancer Research 1

Panel Date: October 6, 2015 Report Date: October 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Basic Cancer Research 1 peer review of applications for FY16 funding. The meeting was chaired by Tom Curran and held at the Marriott Suites Medical/Market Center in Dallas TX on October 6, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Basic Cancer Research 1 panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Tom Curran on October 6, 2015.

The independent observer noted the following during our observation:

- Thirty applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Eighteen peer review panelists, two advocate reviewers, three CPRIT staff members and six SRA employees were present for the meeting.
 - One of the eighteen peer review panelists participated via teleconference.
 - One of the two advocate reviewers participated via teleconference.
- Two conflicts of interest were identified prior to or during the meeting. Applications for one conflict
 was discussed during the peer review panel. The reviewer with the conflict of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical
or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Research Peer Review Observation Report

Report #2015-10-07-RES

Program Name: Academic Research

Panel Name: FY16.1 Cancer Biology

Panel Date: October 7, 2015 Report Date: October 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Cancer Biology peer review of applications for FY16 funding. The meeting was chaired by Peter Jones and held at the Marriott Suites Medical/Market Center in Dallas TX on October 7, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Cancer Biology panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Peter Jones on October 7, 2015.

The independent observer noted the following during our observation:

- Twenty-two applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Fifteen peer review panelists, two advocate reviewers, two CPRIT staff members and five SRA
 employees were present for the meeting.
 - o Two of the fifteen peer review panelists participated via teleconference.
- Seven conflicts of interest were identified prior to or during the meeting. Applications for five conflicts
 were discussed during the peer review panel. The reviewers with the conflicts of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Scientific Review Council Meeting Observation Report

Report #2015-10-23-RES

Program Name: Academic Research

Panel Name: FY16.1 Scientific Review Council

Meeting

Panel Date: October 23, 2015 Report Date: October 27, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Scientific Review Council Meeting peer review of applications for FY16 funding. The meeting was chaired by Richard Kolodner and held via teleconference on October 23, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Scientific Review Council Meeting held via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Richard Kolodner on October 23, 2015.

The independent observer noted the following during our observation:

- Over the course of the call, a review of the scoring for the 65 recommended applications was completed to ensure that they would in fact be recommended for funding. A score cut-off was reinforced by the panel as to which applications will move forward.
- Six peer review panelists, two CPRIT staff members and one SRA employee were present for the meeting.
- No conflicts of interest were identified prior to or during the meeting.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Academic Research Cycle 16.1 Applications (Academic Research Cycle 16.1 Awards Announced at November 19, 2015 Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Cycle 16.1 include Individual Investigator Research Awards, Individual Investigator Research Awards for Prevention and Early Detection, Individual Investigator Research Awards for Cancer in Children and Adolescents, Individual Investigator Research Awards for Computational Biology, and Research Training Awards. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
RP160183pe/ RP160183	Davies, Michael	The University of Texas M. D. Anderson Cancer Center	McMahon, Martin
RP160471pe/ RP160471	Draetta, Giulio	The University of Texas M. D. Anderson Cancer Center	Courtneidge, Sara
RP160013pe/ RP160013	Kundra, Vikas	The University of Texas M. D. Anderson Cancer Center	Riddell, Stanley; Engelhard, Victor
RP160188pe/ RP160188	Schluns, Kimberly	The University of Texas M. D. Anderson Cancer Center	Engelhard, Victor
RP160482pe/ RP160482	Heimberger, Amy	The University of Texas M. D. Anderson Cancer Center	Engelhard, Victor
RP160577pe/ RP160577	Poojary, Venuprasad	Baylor Research Institute	Cooney, Kathleen
RP160497pe/ RP160497	Krishnan, Sunil	The University of Texas M. D. Anderson Cancer Center	Berbeco, Ross
RP160589	Chapkin, Robert	Texas AgriLife Research	Fearon, Eric; Greene, Geoffrey

Application ID	Applicant	Institution	Conflict Noted
RP160015	Ness, Roberta	The University of Texas	Haiman, Christopher;
KI 100013	rvess, reocetta	Health Science Center at	Kushi, Lawrence
		Houston	Rushi, Lawrence
RP160030	Gerber, David	The University of Texas	Barlow, William
KI 100050	Gerber, Buvia	Southwestern Medical	Darrow, william
		Center	
RP160097	Spitz, Margaret	Baylor College of	Martinez, Maria
100077	Spitz, Margaret	Medicine	, wara
RP160145	Bast, Robert	The University of Texas	Kushi, Lawrence; Li,
	,	MD Anderson Cancer	Christopher
		Center	P
Applications	Not Recommended for	PIC or Oversight Commi	ttee Consideration
RP160117pe/	Chen, Benjamin	The University of Texas	Bart Williams
RP160117*	Chen, Benjamin	Southwestern Medical	Dart Williams
111 100117		Center	
RP160472pe	Cox, Marc	The University of Texas	McMahon, Martin
r ·	,	at El Paso	,
RP160079pe	Saikumar, Pothana	The University of Texas	Sonenberg, Nahum
•	ŕ	Health Science Center at	J.
		San Antonio	
RP160113pe	Davis, Anthony	The University of Texas	Tomkinson, Alan;
		Southwestern Medical	Chazin, Walter
		Center	
RP160304pe	Denicourt, Catherine	The University of Texas	Petrini, John
		Health Science Center at	
		Houston	
RP160335pe/	Wang, Bin	The University of Texas	Matthew Weitzman
RP160335*		M. D. Anderson Cancer	
DD4 (02=1	D 4 D 11	Center	TD 1: A1
RP160374pe	Boothman, David	The University of Texas	Tomkinson, Alan
		Southwestern Medical	
DD1/0/11mg	Sahiff Daahal	Center Paylor Callaga of	Datrini John
RP160611pe	Schiff, Rachel	Baylor College of Medicine	Petrini, John
RP160621pe	Latham, Michael	Texas Tech University	Petrini, John
RP160506pe	Aiden, Erez	Baylor College of	Bernstein, Bradley;
111 100300рс	1114011, 11101	Medicine Medicine	Hahn, William
RP160537pe	Kim, Min	The Methodist Hospital	Wahl, Geoffrey
111 1000 / pc		Research Institute	, Sourier
RP160477pe	Hassan, Manal	The University of Texas	Petersen, Gloria;
P		M. D. Anderson Cancer	Martinez, Maria
		Center	
	I.	1	1

Application ID	Applicant	Institution	Conflict Noted
RP160076pe	Jha, Mithilesh	The University of Texas Health Science Center at San Antonio	Hochster, Howard
RP160143pe/ RP160143	Nurieva, Roza	The University of Texas M. D. Anderson Cancer Center	Stadler, Walter; Engelhard, Victor
RP160176pe/ RP160176*	Sharma, Padmanee	The University of Texas M. D. Anderson Cancer Center	Riddell, Stanley
RP160230pe	Trippier, Paul	Texas Tech University Health Sciences Center	Balk, Steven
RP160336pe/ RP160336*	Diab, Adi	The University of Texas M. D. Anderson Cancer Center	Engelhard, Victor
RP160359pe	Bhattacharya, Pratip	The University of Texas M. D. Anderson Cancer Center	Haas-Kogan, Daphne
RP160580pe	Biros, George	The University of Texas at Austin	Mitchell, Duane
RP160645pe/ RP160645*	Jo, Javier	Texas Engineering Experiment Station	Liu, Jonathan; Sutcliffe, Julie
RP160648pe/ RP160648*	Chen, Wei	The University of Texas at Arlington	Zinn, Kurt
RP160222	Rao, Hai	The University of Texas Helath Science Center at San Antonio	Carol Prives
RP160373	Naora, Honami	The University of Texas MD Anderson Cancer Center	Greene, Geoffrey
RP160395*	Lee, Min Gyu	The University of Texas MD Anderson Cancer Center	Belinksy, Steven
RP160535	Kang, Min	Texas Tech University Health Sciences Center	DeClerck, Yves
RP160567*	Zhang, Michael	The University of Texas at Dallas	Lowlor, Elizabeth
RP160168	Felini, Martha	University of North Texas Health Science Center at Fort Worth	Olshan, Andrew
RP160224	Schick, Vanessa	The University of Texas Health Science Center at Houston	Brandon, Thomas

Application ID	Applicant	Institution	Conflict Noted
RP160354*	Stingo, Francesco	The University of Texas MD Anderson Cancer Center	Barlow, William; Li, Christopher; Peterson, Gloria
RP160408*	Shen, Qiang	The University of Texas MD Anderson Cancer Center	Kumar, Nagi
RP160470	Valerio, Melissa	The University of Texas Health Science Center at Houston	Kushi, Lawrence
RP160499*	Minnix, Jennifer	The University of Texas MD Anderson Cancer Center	Brandon, Thomas; Schnoll, Robert
RP160527	Hanash, Samir	The University of Texas MD Anderson Cancer Center	Barlow, William; Li, Christopher; Mucci, Lorelei
RP160554	Bondy, Melissa	Baylor College of Medicine	Haiman, Christopher; Martinez, Maria
RP160587	Wetter, David	Rice University	Brandon, Thomas
RP160525*	Jiang, Ning	The University of Texas at Austin	Press, Oliver; Riddell, Stanley
RP160540	Reynolds, Charles	Texas Tech University Health Sciences Center	Grupp, Stephen; Kast, W. Martin;
RP160466	Yuan, Baohong	University of Texas at Arlington	Zinn, Kurt

De-Identified Overall Evaluation Scores

Individual Investigator Research Awards for Computational Biology

Academic Research Cycle 16.1

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within the Individual Investigator Research Awards mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

This comprehensive list of Individual Investigator Research Awards de-identified application scores created for the purpose of this CEO affidavit packet combines the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not.

Application ID	Final Overall
	Evaluation Score
RP160622*	2.1
ea	2.7
eb	2.9
ec	3.1
ed	3.1
ee	3.3
ef	3.4
eg	3.4
eh	3.7
ei	3.7
ej	3.8
ek	3.9
el	3.9
em	3.9
en	4.0
eo	4.0
ер	4.0
eq	4.0
er	4.1
es	4.3
Et	4.3
eu	4.3
ev	4.3
ew	4.3
ex	4.3
ey	4.3
ez	4.3

^{* =}Recommended for funding

Application ID	Final Overall
	Evaluation Score
fa	4.3
fb	4.5
fc	4.7
fd	4.7
fe	4.7
ff	4.7
fg	5.0
fh	5.0
fi	5.0
fj	5.3
fk	5.3
fl	5.3
fm	5.7
fn	5.7
fo	5.7
fp	6.0
fq	6.3
fr	6.3
fs	6.3
ft	6.7
fu	7.0
fv	7.0
fw	8.7

Final Overall Evaluation Scores and Rank Order Scores





Ludwig Institute for Cancer Research Ltd October 29, 2015

Richard D. Kolodner Ph.D.

Director, San Diego Branch

Head, Laboratory of Cancer Genetics San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

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San Diego Branch

UC San Diego School of Medicine CMM-East / Rm 3058 9500 Gilman Dr - MC 0669 La Jolla, CA 92093-0669

T 858 534 7804 **F** 858 534 7750

Mr. Pete Geren

Oversight Committee Presiding Officer Cancer Prevention and Research Institute of Texas Via email to pgcprit@sidrichardson.org

Mr. Wayne R. Roberts Chief Executive Officer Cancer Prevention and Research Institute of Texas Via email to wroberts@cprit.state.tx.us

Dear Mr. Geren and Mr. Roberts,

In reviewing the list of recommended applications, we were made aware of one minor error in scoring. Application RP160268 was assigned a score of 2.6 in the list, and the actual score should be 2.7. This recommended application was initially placed in row 41 and now appears in row 44. The change of score is reflected in the attached revised list. This does not change the outcome of the SRC recommendation.

Sincerely yours,

Richard D. Kolodner, Ph.D.

Chair, CPRIT Scientific Review Council





Ludwig Institute for Cancer Research Ltd October 29, 2015

Richard D. Kolodner Ph.D.

Director, San Diego Branch

Head, Laboratory of Cancer Genetics San Diego Branch

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Mr. Wayne R. Roberts Chief Executive Officer Cancer Prevention and Research Institute of Texas Via email to wroberts@cprit.state.tx.us

Dear Mr. Geren and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for the Individual Investigator Research Awards (IIRA), Individual Investigator Research Awards for Computational Biology (IIRACB), Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA), Individual Investigator Research Awards for Prevention and Early Detection (IIRAP), Research Training Awards (RTA), and Research Training Awards - Renewal (RTA-R) grant mechanisms. The SRC met on Friday, October 23, 2015 to consider the applications recommended by the peer review panels following their meetings that were held September 29 - October 7, 2015. During the SRC discussion, it was determined that the success rates (percentage of the number recommended/number reviewed) for four panels were much higher than the rates for the other three panels and higher than the historical approval rates. It was suggested that these four panels reduce their success rates to fall in line with the other panels, and all chairs agreed to the scoring adjustments. This resulted in some applications not being recommended for grant awards that received scores equal to or more favorable than some applications that were recommended for grant awards. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded after adjustments were made based on success rates.

Recommended funding amounts and the overall evaluation score are stated for each grant application. The SRC accepted the recommendations of the peer review panels concerning adjustments to three grant applications. These adjustments with justifications are listed at the end of the list of recommended projects. The total amount for the applications recommended is \$62,761,270.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.





Sincerely yours,

Richard D. Kolodner, Ph.D.

Chair, CPRIT Scientific Review Council

Attachment

Rank	App ID	Organization/Company	Application Title	Award Amount	Mech.	Overall Score
Kank	App ID	* *		Amount		Score
	DD1 (0157	The University of Texas	Cancer Intervention and Prevention	Ф2 002 250	RTA-	1.0
1	RP160157	Southwestern Medical Center	Discoveries Program	\$3,993,250	Renewal	1.2
			Decoding Cellular Heterogeneity of			
2	RP160192	Baylor College of Medicine	Malignant Glioma	\$899,701	IIRA	1.3
			Protein Truncation Mutations in WIP1:			
3	RP160451	Baylor College of Medicine	Effects on Cancer and Hematopoiesis	\$900,000	IIRA	1.5
			Development of Therapeutics			
			Targeting Truncated Adenomatous			
			Polyposis Coli (APC) as a Novel			
		The University of Texas	Prevention and Intervention Strategy			
4	RP160180	Southwestern Medical Center	for Colorectal Cancer	\$900,000	IIRA	1.8
			A novel epigenetic reader as			
		The University of Texas M. D.	therapeutic target in MLL-translocated		IIRACC	
5*	RP160237	Anderson Cancer Center	pediatric leukemias	\$900,000	A	1.8
			Baylor College of Medicine			
			Comprehensive Cancer Training		RTA-	
6	RP160283	Baylor College of Medicine	Program	\$3,986,268	Renewal	1.9
		The University of Texas				
_		Health Science Center at San			IIRACC	
7	RP160487	Antonio	Cytokine signaling in Ewing sarcoma	\$1,200,000	A	1.9
			A Randomized Controlled Trial (RCT)			
			of Patient Navigation for Lung Cancer			
	DD1 60000	The University of Texas	Screening in an Urban Safety-Net	01.402 51 5	110 : 5	
8	RP160030	Southwestern Medical Center	System	\$1,492,616	IIRAP	1.9
			Promoting The Functions of Memory T			
9	RP160384	Baylor College of Medicine	cells for Adoptive T cell Therapy	\$887,676	IIRA	1.9
			Role of Long Non-Coding RNAs in			
			Breast Cancer: Identification,			
		The University of Texas	Characterization, and Determination of			
10	RP160318	Southwestern Medical Center	Molecular Functions	\$886,652	IIRA	2.0

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			Arylhydrocarbon receptor mediated			
			modulation of colorectal cancer by			
11	RP160589	Texas AgriLife Research	microbiota metabolites	\$890,840	IIRAP	2.0
- 11	Kt 100507	Texas rigitalite Research	Pediatric Radiation Oncology with	\$670,040	IIIQ II	2.0
		The University of Texas	Movie Induced Sedation Effect		IIRACC	
12**	RP160190	Southwestern Medical Center	(PROMISE)	\$900,000	A	2.0
12	100170	The University of Texas M. D.	Amplified gold nanoparticle-mediated	Ψ>00,000	7.1	2.0
13	RP160497	Anderson Cancer Center	radiosensitization of tumors	\$899,309	IIRA	2.0
13	KI 100497	Anderson Cancer Center	Imaging-based quantitative analysis of	\$699,509	ШХА	2.0
			vascular perfusion and tissue			
		The University of Texas M. D.	oxygenation to improve therapy of			
14	RP160229	Anderson Cancer Center	hepatocellular carcinoma	\$885,901	IIRA	2.0
11	10022	7 maerson cancer center	Molecular Mechanism of NLRP12-	ψουσ,5 σ 1	11101	2.0
		The University of Texas	mediated Regulation of Colorectal			
15	RP160169	Southwestern Medical Center	Cancer	\$897,707	IIRA	2.1
		The University of Texas	DIS3L2 in Childhood Wilms Tumor:	, , , , , ,	IIRACC	
16***	RP160249	Southwestern Medical Center	Mechanism to Medicines	\$1,200,000	A	2.1
10	100249	Southwestern Medical Center	Carbamoyl Phosphate Synthase-1: A	ψ1,200,000	F 1	۷.1
		The University of Texas	new metabolic liability in non-small			
17	RP160089	Southwestern Medical Center	cell lung cancers	\$900,000	IIRA	2.1
17	100000	The Methodist Hospital	De-Orphanizing TLX: Implications for	Ψ>00,000	11101	2.1
18	RP160501	Research Institute	Glioblastomas	\$878,969	IIRA	2.1
10	KI 100301		Gilobiastomas	\$676,909	IIIA	2.1
10	DD1 (0 (22	The University of Texas		#20 2 770	HD 4 GD	2.1
19	RP160622	Southwestern Medical Center	Computational live cell histology	\$392,779	IIRACB	2.1
			Cancer Prevention Post-Graduate			
20	RP160097	Davier Callege of Medicine	Training Program in Integrative	\$2.096.900	RTA	2.1
20	KF 100097	Baylor College of Medicine The University of Texas	Epidemiology Collaborative Training of a New Cadre	\$2,986,890	KIA	2.1
		Health Science Center at	of Innovative Cancer Prevention		RTA-	
21	RP160015	Houston	Researchers	\$4,000,000	Renewal	2.1
21	KI 100013			\$4,000,000	Renewai	2.1
22	DD160240	The University of Texas	The role of the Lats kinases in	\$000 500	IID A	2.2
22	RP160340	Southwestern Medical Center	sarcomatoid renal cell carcinoma	\$899,598	IIRA	2.2
			Exploiting molecular and metabolic			
		The University of Texas M. D.	dependencies to optimize personalized			
23	RP160183	Anderson Cancer Center	therapeutic approaches for melanomas	\$900,000	IIRA	2.2
			Understanding Biological and Physical			
		m	Factors Affecting Response to Proton			
2.4	DD1 (0222	The University of Texas M. D.	Therapy to Improve its Clinical	4070 272	IID 4	2.2
24	RP160232	Anderson Cancer Center	Effectiveness	\$879,362	IIRA	2.2
			Role of Cohesin in Hematopoiesis and		IID A CC	
25	DD160022	Dealer Callege - CM- Hair	Myeloid Leukemia in Children with	¢1.005.639	IIRACC	2.2
25	RP160022	Baylor College of Medicine	Down Syndrome	\$1,905,638	A	2.2
		The University of Texas M. D.	Mechanisms and targeting strategies for			
26	RP160242	Anderson Cancer Center	SWI/SNF mutations in cancer	\$900,000	IIRA	2.3
			Targeting the undruggable: a first-in-			
	DD160446	The University of Texas	class inhibitor of the HIF-2	4000 11	TIP :	2.2
27	RP160440	Southwestern Medical Center	transcription factor	\$899,412	IIRA	2.3

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28	RP160145	The University of Texas M. D. Anderson Cancer Center	Early Detection of Ovarian Cancer with Tumor Associated Proteins and Autoantibodies	\$1,497,595	IIRAP	2.3
29	RP160013	The University of Texas M. D. Anderson Cancer Center	Visualizing T-cell trafficking	\$900,000	IIRA	2.3
30	RP160019	The University of Texas M. D. Anderson Cancer Center	An Adaptive Personalized Clinical Trial using a Patient-Derived Xenograft Strategy to Overcome Ibrutinib Resistance in Mantle Cell Lymphoma	\$841,606	IIRA	2.3
31	RP160051	Texas A&M University System Health Science Center	Improving contrast for antibody-based tumor detection using PET	\$887,134	IIRA	2.3
32	RP160023	The University of Texas M. D. Anderson Cancer Center	Investigating the genetic and molecular mechanisms underlying RAS/ERK substrate network Novel tumorigenic mechanisms of the	\$900,000	IIRA	2.4
33	RP160211	The University of Texas Southwestern Medical Center	LKB1 tumor suppressor in endometrial and cervical cancer	\$896,653	IIRA	2.4
34	RP160319	The University of Texas Southwestern Medical Center	Role of PARP-1 in Estrogen Receptor Enhancer Function and Gene Regulation Outcomes in Breast Cancers	\$884,315	IIRA	2.4
35	RP160124	The University of Texas Health Science Center at San Antonio	Chemoprevention of Colon Cancer by Anti-inflammatory Blockade Using Neem	\$899,617	IIRAP	2.4
36	RP160188	The University of Texas M. D. Anderson Cancer Center	Regulation of infiltration and function of tumor-resident CD8 T cells by IL-15	\$828,060	IIRA	2.4
37	RP160255	The University of Texas Southwestern Medical Center	Structural and Functional Analyses of the Spindle Checkpoint	\$900,000	IIRA	2.5
38	RP160307	The University of Texas Southwestern Medical Center	Targeting Metastatic Pathways	\$900,000	IIRA	2.5
39	RP160517	The University of Texas M. D. Anderson Cancer Center	Exosomal DNA as a surrogate biomarker for early diagnosis and therapeutic stratification in pancreatic cancer	\$891,938	IIRA	2.5
40	RP160345	Baylor College of Medicine	Engineering T cells to ensure specificity for tumor cells and their environment	\$900,000	IIRA	2.5
41	RP160482	The University of Texas M. D. Anderson Cancer Center	Nanoparticle Targeted STAT3 Immune Expression Clinical Safety and Efficacy of Third	\$888,429	IIRA	2.6
42	RP160121	The University of Texas M. D. Anderson Cancer Center	party, fucosylated, cord blood derived regulatory T cells to prevent graft versus host disease	\$900,000	IIRA	2.6
43	RP160520	The University of Texas Southwestern Medical Center	Effect of Chest Radiation Therapy on Cardiomyocyte Turnover	\$897,570	IIRAP	2.6
44	RP160268	The University of Texas Southwestern Medical Center	DNA damage-induced small non- coding RNAs: mechanism and their role in cancer development	\$900,000	IIRA	2.7

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San Diego

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	ı	Г	T			
			Integrin-mediated IL-18 signaling in			
		The University of Texas	the prevention and treatment of			
		Health Science Center at San	inflammation-associated colorectal			
45	RP160512	Antonio	cancer	\$859,620	IIRA	2.7
			A novel function of Itch in controlling			
			IL-17-induced inflammation in colon			
46	RP160577	Baylor Research Institute	cancer	\$900,000	IIRA	2.7
			Optimizing therapeutic strategies			
		The University of Texas at	against lung cancer using Multi-			
47	RP160617	Dallas	Modality Imaging	\$899,999	IIRA	2.7
			Characterization and pharmacological			
		The University of Texas	targeting of the oncogenic activity of			
48	RP160493	Southwestern Medical Center	Jumonji enzymes	\$899,997	IIRA	2.8
			The CTC Circulator Phenotype:	Í		
			Insights into Mechanisms of Breast			
49	RP160054	Baylor College of Medicine	Cancer Dormancy	\$884,332	IIRA	2.9
49	KF 100034	The University of Texas	Regulation of tumor aggressiveness and	\$664,332	IINA	2.9
		Health Science Center at	immune suppression in lung			
50	DD160225		adenocarcinoma	000 000	IID A	2.0
50	RP160235	Houston	1	\$900,000	IIRA	2.9
			Radiogenomic Screen to Identify Novel			
			Proliferation-associated Glioblastoma			
			Genomic Therapeutic Targets:			
5.1	DD1 601 50	The University of Texas M. D.	Discovery and Mechanistic Validation	#00 7.637	IID 4	2.0
51	RP160150	Anderson Cancer Center	Study	\$897,627	IIRA	3.0
			High resolution imaging for early and			
52	RP160460	Rice University	better detection of bladder cancer	\$873,765	IIRAP	3.0
		The University of Texas M. D.	Identifying new epigenetic	·		
53	RP160471	Anderson Cancer Center	vulnerabilities in pancreatic cancer	\$900,000	IIRA	3.1
- 55	10 100 1/1	- Indiana Canton Conton	Systematic identification of small	Ψ>00,000	11141	5.1
			molecule inhibitors that manipulate			
54	RP160462	Baylor College of Medicine	telomerase activities	\$898,288	IIRA	3.2
J-T	100402	Buylor Conege of Wicdichie	The role of Prdm16 and histone H3	\$676,200	шил	J.L
			lysine 9 methyltransferase complex in			
55	RP160035	Baylor College of Medicine	MDS	\$872,157	IIRA	3.2
33	KI 100033	Daylor College of Medicille	MIDS	\$6/4,13/	ШХА	3.4

^{*}RP160237 - The peer review panel recommended reducing the budget to \$300,000 per year for 3 years for a total of \$900,000 based on the scope and depth of the work proposed.

^{**}RP160190 - The peer review panel recommended not funding Aim 4 (Pilot prospective clinical trial) and reducing the budget to \$300,000 per year for 3 years for a total of \$900,000. The final score was based on revised scope with full deletion of Aim 4.

^{***}RP160249 - The peer review panel recommended that given the absence of a clinical trial, the budget should be reduced to \$300,000 per year for 4 years for a total of \$1,200,000.





Success Rate by Panel				
Peer Review	Success	Score		
Panel	Rate	Cutoff		
BCR1	10%	2.3		
BCR2	11%	3.2		
СВ	9%	3.2		
CPR	9%	2.4		
CTCR/TCR	13%	2.7		
ITI	11%	3.0		

Success Rate by Mechanism vs. Total Reviewed					
Mechanism	Success Rate	# Recommended			
IIRA	11%	39/347			
IIRACB	2%	1/50			
IIRACCA	11%	5/44			
IIRAP	13%	6/44			
RTA	14%	1/7			
RTA-R	50%	3/6			
Overall	11%	55/498			

Percent of Applications Recommended by				
Mechanism vs. Total Recommended				
Mechanism	# Recommended	Percentage		
IIRA	39/55	71%		
IIRACB	1/55	2%		
IIRACCA	5/55	9%		
IIRAP	6/55	11%		
RTA	1/55	2%		
RTA-R	3/55	5%		
Overall	55/55	100%		



CEO Affidavit Supporting Information

FY 2016—Cycle 1 Individual Investigator Research Awards for Cancer in Children and Adolescents

Request for Applications



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS RFA R-16-IIRACCA-1

Individual Investigator Research Awards for Cancer in Children and Adolescents

Please also refer to the Instructions for Applicants document, which will be posted on March 20, 2015

Application Receipt Opening Date: March 20, 2015 **Application Receipt Closing Date:** May 20, 2015

FY 2016

Fiscal Year Award Period September 1, 2015-August 31, 2016

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RFA VERSION HISTORY

Rev 02/20/15 RFA release

1. ABOUT CPRIT

The state of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the
 potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the state of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The principles and priorities of the Scientific Research program will guide CPRIT staff, peer reviewers, and the Scientific Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs. The program priorities for research adopted by the Oversight Committee include funding projects that address:

- A broad range of innovative, investigator-initiated research projects;
- Prevention and early detection;
- Rare and intractable cancers, including childhood cancers;
- Cancers of importance in Texas;
- Computational biology and analytic methods; and
- Building Infrastructure.

2. RATIONALE

In recent decades, great strides have been made in reducing mortality from childhood cancers. Most of these gains have been realized in childhood leukemia and lymphoma. However, improvements in survival have been less robust in other types of childhood cancers, which make up more than 40% of total cancer cases in children and adolescents aged 0 to 19 years.

Furthermore, the overall incidence of pediatric cancer has increased at an annual rate of 0.6% since 1975, with most of the increases being seen in acute lymphocytic leukemia, brain and central nervous system tumors, non-Hodgkin's lymphoma, and testicular germ cell tumors. Reasons for increases in these tumor types are unknown, indicating that information on the etiology of these cancers is urgently needed. Because of the high rates of survival for certain childhood and adolescent cancers, there are increasing numbers of survivors of such cancers living today. These individuals have a high rate of late effects from the cancer or its treatment, including the occurrence of additional cancers. Clearly, more effective, less toxic treatments are needed for these diseases. However, few new therapies have been developed in recent years. Several reasons account for the paucity of new treatments, including the lack of interest on the part of pharmaceutical companies in developing treatments for cancers that account for only 1% of all cancer cases and the difficulty of collecting sufficient numbers of tumors for laboratory studies.

Because cancers in children and adolescents differ from those in adults with regard to genetic alterations and biological behavior, application of adult therapies to these cancers may not be successful. Therefore, this area of investigation represents an opportunity for CPRIT to deploy funding in an area of critical need that is not heavily represented in other funding portfolios.

3. RESEARCH OBJECTIVES

This Request for Applications (RFA) solicits applications from individual investigators for innovative research projects addressing questions that will advance current knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. Applications may address any topic related to these areas as well as projects dealing with the causes or amelioration of late effects of cancer treatment. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near or long term. Applications that seek to apply or develop state-of-the-art approaches, technologies, tools, treatments, and/or resources are encouraged, particularly those with potential for commercialization. Successful applicants should be working in a research environment capable of supporting potentially high-impact studies.

The subject of applications may include, but is not limited to, the following:

 Causes of cancer in children and adolescents, including genetic factors or prenatal exposure to environmental agents;

- Identification of risk factors for cancer development;
- New methods for diagnosing cancers in children and/or adolescents;
- Development of new therapies, including targeted therapies, immunotherapies, and new drugs;
- Identification of patients at risk of developing late effects of cancer treatment;
- Improvements in quality of life for survivors of childhood and adolescent cancers.

The *degree of relevance* to reducing the burden of cancer in these populations will be an important criterion for evaluation of projects for funding by CPRIT.

4. FUNDING INFORMATION

Applicants may request a maximum of \$500,000 per year for a period of up to 4 years. Exceptions to these limits may be requested if extremely well justified. Applications funded in this cycle will be eligible for competitive renewal. Funds may be used for salary and fringe benefits, research supplies, equipment, subject participation costs, and travel to scientific/technical meetings or collaborating institutions. Requests for funds to support construction and/or renovation will not be approved under this funding mechanism. State law limits the amount of award funding that may be spent on indirect costs to no more than 5% of the total award amount.

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization
 that conducts research is eligible to apply for funding under this award mechanism.
 A public or private company is not eligible for funding under this award mechanism;
 these entities must use the appropriate award mechanism(s) under CPRIT's Product
 Development Program.
- The Principal Investigator (PI) must have a doctoral degree, including MD, PhD, DDS,
 DMD, DrPH, DO, DVM, or equivalent and must reside in Texas during the time the research that is the subject of the grant is conducted.
- A PI may submit only 1 new application under this RFA during this funding cycle. A PI may not submit applications to this RFA and to RFA-R-16-IIRA-1, RFA-R-16-IIRACB-1 or RFA R-16-IIRAP. Only 1 IIRACB, IIRACCA, IIRA, or IIRAP application per cycle is allowed. An investigator who is the PI on 3 or more CPRIT grants of any type that will

- be active December 1, 2015 is not eligible to submit an application in response to this RFA.
- Applications that address untargeted research, Prevention and Early Detection, or Computational Biology should be submitted under the appropriate targeted RFA.
- Because this award mechanism is intended to support research directed by a single investigator, only 1 Co-PI may be included.
- Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the state of Texas, but non— Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant is eligible to receive a grant award only if the applicant certifies that the
 applicant institution or organization, including the PI, any senior member or key
 personnel listed on the grant application, and any officer or director of the grant
 applicant's institution or organization (or any person related to 1 or more of these
 individuals within the second degree of consanguinity or affinity), has not made and will
 not make a contribution to CPRIT or to any foundation specifically created to benefit
 CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PI, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the PI, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds, or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. RESUBMISSION POLICY

An application previously submitted to CPRIT but not funded may be resubmitted once and must follow all resubmission guidelines. More than 1 resubmission is not permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PI for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission. This policy is in effect for all applications submitted to date. See section 8.2.5.

7. RENEWAL POLICY

An application originally funded by CPRIT as an IIRA that is appropriate for the IIRACCA mechanism may be submitted under this RFA for a competitive renewal. See <u>section 8.2.5</u>. Competitive renewals are not subject to preliminary evaluation. Renewal applications move directly to the full peer review phase. See <u>section 9.2</u>.

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and submit an application. The Co-PI, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (ASO) (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on March 20, 2015, and must be submitted by 3 PM central time on May 20, 2015. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

8.1.1. Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via email to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in <u>section 5</u> will be administratively withdrawn without review.

8.2.1. Abstract and Significance (5,000 characters)

Clearly explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the Research Plan. Clearly address how the proposed project, if successful, will have a major impact on cancer. Summarize how the proposed research creates new paradigms or challenges existing ones. Indicate whether this research plan represents a new direction for the PI.

Note: It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance statement alone. Therefore, applicants are advised to prepare this section wisely. Applicants should not waste this valuable space by stating obvious facts (eg, that cancer is a significant problem; that better diagnostic and therapeutic approaches are needed urgently; or that the type of cancer of interest to the PI is important, vexing, or deadly). Based on this statement (and the Budget and Justification and Biographical Sketches), applications that are judged to offer only modest contributions to the field of cancer research or that do not sufficiently capture the reviewers' interest may be excluded from further peer review (see section 9.1).

8.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer research, early diagnosis, prevention, or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Do not include any proprietary information in the Layperson's Summary. The Layperson's Summary will also be used by advocate reviewers (section 9.2) in evaluating the significance and impact of the proposed work.

8.2.3. Goals and Objectives

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success.

8.2.4. Timeline (1 page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.5. Resubmission Summary (1 Page)

Applicants preparing a resubmission must describe the approach to the resubmission. If a summary statement was prepared for the original application review, applicants are advised to address all noted concerns.

Note: An application previously submitted to CPRIT but not funded may be resubmitted once after careful consideration of the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a fresh Research Plan or modify the original Research Plan and mark the changes. However, all resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

8.2.6. Renewal Summary (2 pages)

Applicants preparing a renewal must describe and demonstrate that appropriate/adequate progress has been made on the current funded award to warrant further funding. Publications and manuscripts in press that have resulted from work performed during the initial funded period should be listed in the renewal summary.

8.2.7. Research Plan (10 pages)

Background: Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed.

Hypothesis and Specific Aims: Concisely state the hypothesis and/or specific aims to be tested or addressed by the research described in the application.

Research Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data that support the proposed hypothesis are encouraged but not required.

8.2.8. Vertebrate Animals and/or Human Subjects (1 page)

If vertebrate animals will be used, provide an outline of the appropriate protocols that will be followed. If human subjects or human biological samples will be used, provide a plan for recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism.

8.2.9. Publications/References

Provide a concise and relevant list of publications/references cited for the application.

8.2.10. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. Do not exceed \$500,000 per year over a maximum period of 4 years. Applicants are advised not to interpret the maximum allowable time and funding under this award as a suggestion that they should expand their anticipated work and budget to this level. Reasonable budgets clearly work in favor of the applicant.

However, if there is a highly specific and defensible need to request more than the maximum amount in any year(s) of the proposed budget, include a special and clearly labeled section in the budget justification that explains the request. Poorly justified requests of this type will likely have a negative impact on the overall evaluation of the application.

In preparing the requested budget, applicants should be aware of the following:

- Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. So-called grants management and facilities fees (eg, sponsored programs fees; grants and contracts fees; electricity, gas, and water; custodial fees; maintenance fees) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.
- The annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2016 is \$200,000; CPRIT FY 2016 is from September 1, 2015, through August 31, 2016. Salary does not include fringe benefits and/or facilities and administrative (F&A) costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

8.2.11. Biographical Sketches (2 pages each)

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. A biographical sketch must be provided for the PI and, if applicable, the Co-PI (as required by the online application receipt system). Up to 2 additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed 2 pages.

8.2.12. Current and Pending Support

Describe the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title, a 2-line summary of the goal of the project and, if relevant, a statement of overlap with the current application. At a minimum, current and pending support of the PI and, if applicable, the Co-PI must be provided.

8.2.13. Institutional/Collaborator Support and/or Other Certification (4 pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 4 pages may be provided.

8.2.14. Previous Summary Statement

If the application is being resubmitted, the summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission. The applicant is not responsible for providing this document.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively rejected without review.

9. APPLICATION REVIEW

9.1. Preliminary Evaluation

To ensure the timely and thorough review of only the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, all eligible applications may be preliminarily evaluated by CPRIT Scientific Research Program panel members for scientific merit and impact.

This preliminary evaluation will be based on a subset of material presented in the application—namely Abstract and Significance, Budget and Justification, and Biographical Sketches. Applications that do not sufficiently capture the reviewers' interest at this stage will not be considered for further review. Such applications will have been judged to offer only modest contributions to the field of cancer research and will be excluded from further peer review.

The applicant will be notified of the decision to disapprove the application after the preliminary evaluation stage has concluded. Due to the volume of applications to be reviewed, comments made by reviewers at the preliminary evaluation stage may not be provided to applicants. The preliminary evaluation process will be used only when the number of applications exceeds the capacity of the review panels to conduct a full peer review of all received applications.

9.2. Full Peer Review

Applications that pass preliminary evaluation will undergo further review using a 2-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts as well as advocate reviewers using the criteria listed below. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by Scientific Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC.

The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

9.3. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Peer Review Panel members and Scientific Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. **By submitting** a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: An Oversight Committee Member, a PIC Member, a Scientific Review Panel member, or a Scientific Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services.

The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

9.4. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.

9.4.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study. Primary criteria include the following:

Significance and Impact: Will the results of this research, if successful, significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for patients? Is the application innovative? Does the applicant propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important underexplored or unexplored areas? If the research project is successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? Projects that modestly extend current lines of research will not be considered for this award. Projects that represent straightforward extensions of ongoing work, especially work traditionally funded by other mechanisms, will not be competitive.

Research Plan: Is the proposed work presented as a self-contained research project? Does the proposed research have a clearly defined hypothesis or goal that is supported by sufficient preliminary data and/or scientific rationale? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed?

Applicant Investigator: Does the applicant investigator demonstrate the required creativity and expertise to make a significant contribution to the research? Applicants' credentials will be evaluated in a career stage—specific fashion. Have early career—stage investigators received excellent training, and do their accomplishments to date offer great promise for a successful career? Has the applicant devoted a sufficient amount of his or her time (percentage effort) to this project?

Relevance: Does the proposed research address cancer in children or adolescents? Is it likely to make an impact on these diseases? This will be an important criterion for evaluation of projects for CPRIT support.

9.4.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed research.

Secondary criteria include the following:

Research Environment: Does the research team have the needed expertise, facilities, and resources to accomplish all aspects of the proposed research? Are the levels of effort of the key personnel appropriate? Is there evidence of institutional support of the research team and the project?

Vertebrate Animals and/or Human Subjects: If vertebrate animals and/or human subjects are included in the proposed research, certification of approval by the institutional IACUC and/or IRB, as appropriate, will be required before funding can occur.

Budget: Is the budget appropriate for the proposed work?

Duration: Is the stated duration appropriate for the proposed work?

10. KEY DATES

RFA

RFA release February 20, 2015

Application

Online application opens March 20, 2015, 7 AM central time

Application due May 20, 2015, 3 PM central time

Application review September - October 2015

Award

Award notification November 2015

Anticipated start date March 2016

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to

exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. Applicants are advised to review CPRIT's administrative rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed, and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements regarding demonstration of available funding.

13. CONTACT INFORMATION

13.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding scientific aspects of applications.

Dates of operation: February 20 – May 20, 2015 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time

Wednesday, 8 AM to 4 PM central time

Tel: 866-941-7146

E-mail: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Senior Manager for Research.

Tel: 512-305-8491

Email: <u>Help@CPRITGrants.org</u>

Website: www.cprit.state.tx.us

Third Party Observer Reports



CPRIT Research Peer Review Observation Report

Report #2015-09-29-RES

Program Name: Academic Research

Panel Name: FY16.1 Clinical & Translational Cancer

Research and Translational Cancer Research

Panel Date: September 29, 2015 Report Date: October 7, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Clinical & Translational Cancer Research and Translational Cancer Research peer review of applications for FY16 funding. The meeting was co-chaired by Richard O'Reilly and Margaret Tempero and held at the Marriott Suites Medical/Market Center in Dallas TX on September 29, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Clinical & Translational Cancer Research and Translational Cancer Research panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and co-chaired by Richard O'Reilly and Margaret Tempero on September 29, 2015.

The independent observer noted the following during our observation:

- Twenty-four applications were discussed within the Research Peer Review Meeting to determine which
 grants would receive CPRIT funding.
- Twenty-six peer review panelists, three advocate reviewers, three CPRIT staff members and five SRA employees were present for the meeting.
 - o Two of the twenty-six peer review panelists participated via teleconference.
- Thirteen conflicts of interest were identified prior to or during the meeting. Applications for nine
 conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest either
 left the room or did not participate telephonically and did not participate in the review of the conflicted
 application.
 - One of the nine conflicts did not sign out on the conflict of interest sign out sheet when leaving the room.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Research Peer Review Observation Report

Report #2015-09-30-RES

Program Name: Academic Research

Panel Name: FY16.1 Cancer Prevention Research

Panel Date: September 30, 2015 Report Date: October 7, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Cancer Prevention Research peer review of applications for FY16 funding. The meeting was chaired by Tom Sellers and held at the Marriott Suites Medical/Market Center in Dallas TX on September 30, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Cancer Prevention Research panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Tom Sellers on September 30, 2015.

The independent observer noted the following during our observation:

- Nineteen applications were discussed within the Research Peer Review Meeting to determine which
 grants would receive CPRIT funding.
- Seventeen peer review panelists, two advocate reviewers, four CPRIT staff members and five SRA
 employees were present for the meeting.
 - One of the seventeen peer review panelists participated via teleconference and for only one application.
- Twenty-one conflicts of interest were identified prior to or during the meeting. Applications for fifteen
 conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest either
 left the room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical
or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Research Peer Review Observation Report

Report #2015-10-01-RES

Program Name: Academic Research

Panel Name: FY16.1 Imaging Technology and

Informatics

Panel Date: October 1, 2015 Report Date: October 7, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Imaging Technology and Informatics peer review of applications for FY16 funding. The meeting was chaired by Sam Gambhir and held at the Marriott Suites Medical/Market Center in Dallas TX on October 1, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Imaging Technology and Informatics panel meeting held inperson. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Sam Gambhir on October 1, 2015.

The independent observer noted the following during our observation:

- Eighteen applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Twenty-one peer review panelists, two advocate reviewers, two CPRIT staff members and five SRA
 employees were present for the meeting.
 - One of the twenty-one peer review panelists participated via teleconference.
- Five conflicts of interest were identified prior to or during the meeting. Applications for two conflicts
 were discussed during the peer review panel. The reviewers with the conflicts of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Research Peer Review Observation Report

Report #2015-10-05-RES

Program Name: Academic Research

Panel Name: FY16.1 Basic Cancer Research 2

Panel Date: October 5, 2015 Report Date: October 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Basic Cancer Research 2 peer review of applications for FY16 funding. The meeting was chaired by Carol Prives and held at the Marriott Suites Medical/Market Center in Dallas TX on October 5, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Basic Cancer Research 2 panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Carol Prives on October 5, 2015.

The independent observer noted the following during our observation:

- Nineteen applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Fifteen peer review panelists, two advocate reviewers, two CPRIT staff members, five SRA employees
 and chair for the Scientific Review Council were present for the meeting.
 - o Two of the fifteen peer review panelists participated via teleconference.
 - One participated for review of only four applications and the other participated as an ad hoc reviewer for one application.
- Two conflicts of interest were identified prior to or during the meeting. Applications for one conflict
 was discussed during the peer review panel. The reviewer with the conflict of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
 - o The reviewer was present when final scores were still visible on projection screen.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Research Peer Review Observation Report

Report #2015-10-06-RES

Program Name: Academic Research

Panel Name: FY16.1 Basic Cancer Research 1

Panel Date: October 6, 2015 Report Date: October 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Basic Cancer Research 1 peer review of applications for FY16 funding. The meeting was chaired by Tom Curran and held at the Marriott Suites Medical/Market Center in Dallas TX on October 6, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Basic Cancer Research 1 panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Tom Curran on October 6, 2015.

The independent observer noted the following during our observation:

- Thirty applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Eighteen peer review panelists, two advocate reviewers, three CPRIT staff members and six SRA
 employees were present for the meeting.
 - One of the eighteen peer review panelists participated via teleconference.
 - One of the two advocate reviewers participated via teleconference.
- Two conflicts of interest were identified prior to or during the meeting. Applications for one conflict
 was discussed during the peer review panel. The reviewer with the conflict of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical
or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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CPRIT Research Peer Review Observation Report

Report #2015-10-07-RES

Program Name: Academic Research

Panel Name: FY16.1 Cancer Biology

Panel Date: October 7, 2015 Report Date: October 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Cancer Biology peer review of applications for FY16 funding. The meeting was chaired by Peter Jones and held at the Marriott Suites Medical/Market Center in Dallas TX on October 7, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Cancer Biology panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Peter Jones on October 7, 2015.

The independent observer noted the following during our observation:

- Twenty-two applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Fifteen peer review panelists, two advocate reviewers, two CPRIT staff members and five SRA
 employees were present for the meeting.
 - o Two of the fifteen peer review panelists participated via teleconference.
- Seven conflicts of interest were identified prior to or during the meeting. Applications for five conflicts
 were discussed during the peer review panel. The reviewers with the conflicts of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Scientific Review Council Meeting Observation Report

Report #2015-10-23-RES

Program Name: Academic Research

Panel Name: FY16.1 Scientific Review Council

Meeting

Panel Date: October 23, 2015 Report Date: October 27, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Scientific Review Council Meeting peer review of applications for FY16 funding. The meeting was chaired by Richard Kolodner and held via teleconference on October 23, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Scientific Review Council Meeting held via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Richard Kolodner on October 23, 2015.

The independent observer noted the following during our observation:

- Over the course of the call, a review of the scoring for the 65 recommended applications was completed to ensure that they would in fact be recommended for funding. A score cut-off was reinforced by the panel as to which applications will move forward.
- Six peer review panelists, two CPRIT staff members and one SRA employee were present for the meeting.
- No conflicts of interest were identified prior to or during the meeting.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Academic Research Cycle 16.1 Applications (Academic Research Cycle 16.1 Awards Announced at November 19, 2015 Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Cycle 16.1 include Individual Investigator Research Awards, Individual Investigator Research Awards for Prevention and Early Detection, Individual Investigator Research Awards for Cancer in Children and Adolescents, Individual Investigator Research Awards for Computational Biology, and Research Training Awards. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted			
App	Applications considered by the PIC and Oversight Committee					
RP160183pe/ RP160183	Davies, Michael	The University of Texas M. D. Anderson Cancer Center	McMahon, Martin			
RP160471pe/ RP160471	Draetta, Giulio	The University of Texas M. D. Anderson Cancer Center	Courtneidge, Sara			
RP160013pe/ RP160013	Kundra, Vikas	The University of Texas M. D. Anderson Cancer Center	Riddell, Stanley; Engelhard, Victor			
RP160188pe/ RP160188	Schluns, Kimberly	The University of Texas M. D. Anderson Cancer Center	Engelhard, Victor			
RP160482pe/ RP160482	Heimberger, Amy	The University of Texas M. D. Anderson Cancer Center	Engelhard, Victor			
RP160577pe/ RP160577	Poojary, Venuprasad	Baylor Research Institute	Cooney, Kathleen			
RP160497pe/ RP160497	Krishnan, Sunil	The University of Texas M. D. Anderson Cancer Center	Berbeco, Ross			
RP160589	Chapkin, Robert	Texas AgriLife Research	Fearon, Eric; Greene, Geoffrey			

Application ID	Applicant	Institution	Conflict Noted
RP160015	Ness, Roberta	The University of Texas	Haiman, Christopher;
KI 100013	ivess, ivoocita	Health Science Center at	Kushi, Lawrence
		Houston	Rushi, Lawrence
RP160030	Gerber, David	The University of Texas	Barlow, William
KI 100050	Gerber, Buvia	Southwestern Medical	Darrow, william
		Center	
RP160097	Spitz, Margaret	Baylor College of	Martinez, Maria
100077	Spitz, margaret	Medicine	, wara
RP160145	Bast, Robert	The University of Texas	Kushi, Lawrence; Li,
	,	MD Anderson Cancer	Christopher
		Center	P
Applications	Not Recommended for	PIC or Oversight Commi	ttee Consideration
RP160117pe/	Chen, Benjamin	The University of Texas	Bart Williams
RP160117*	Chen, Benjamin	Southwestern Medical	Dart Williams
111 100117		Center	
RP160472pe	Cox, Marc	The University of Texas	McMahon, Martin
r ·	,	at El Paso	,
RP160079pe	Saikumar, Pothana	The University of Texas	Sonenberg, Nahum
•	ŕ	Health Science Center at	J.
		San Antonio	
RP160113pe	Davis, Anthony	The University of Texas	Tomkinson, Alan;
		Southwestern Medical	Chazin, Walter
		Center	
RP160304pe	Denicourt, Catherine	The University of Texas	Petrini, John
		Health Science Center at	
		Houston	
RP160335pe/	Wang, Bin	The University of Texas	Matthew Weitzman
RP160335*		M. D. Anderson Cancer	
DD4 (02=1	D 4 D 11	Center	TD 1: 41
RP160374pe	Boothman, David	The University of Texas	Tomkinson, Alan
		Southwestern Medical	
DD1/0/11mg	Schiff, Rachel	Center Paylor Callaga of	Datrini John
RP160611pe	Schill, Rachel	Baylor College of Medicine	Petrini, John
RP160621pe	Latham, Michael	Texas Tech University	Petrini, John
RP160506pe	Aiden, Erez	Baylor College of	Bernstein, Bradley;
111 100300рс	1114011, 12102	Medicine Medicine	Hahn, William
RP160537pe	Kim, Min	The Methodist Hospital	Wahl, Geoffrey
111 1000 / pc		Research Institute	, Storing
RP160477pe	Hassan, Manal	The University of Texas	Petersen, Gloria;
P		M. D. Anderson Cancer	Martinez, Maria
		Center	
	I.	1	1

Application ID	Applicant	Institution	Conflict Noted
RP160076pe	Jha, Mithilesh	The University of Texas Health Science Center at San Antonio	Hochster, Howard
RP160143pe/ RP160143	Nurieva, Roza	The University of Texas M. D. Anderson Cancer Center	Stadler, Walter; Engelhard, Victor
RP160176pe/ RP160176*	Sharma, Padmanee	The University of Texas M. D. Anderson Cancer Center	Riddell, Stanley
RP160230pe	Trippier, Paul	Texas Tech University Health Sciences Center	Balk, Steven
RP160336pe/ RP160336*	Diab, Adi	The University of Texas M. D. Anderson Cancer Center	Engelhard, Victor
RP160359pe	Bhattacharya, Pratip	The University of Texas M. D. Anderson Cancer Center	Haas-Kogan, Daphne
RP160580pe	Biros, George	The University of Texas at Austin	Mitchell, Duane
RP160645pe/ RP160645*	Jo, Javier	Texas Engineering Experiment Station	Liu, Jonathan; Sutcliffe, Julie
RP160648pe/ RP160648*	Chen, Wei	The University of Texas at Arlington	Zinn, Kurt
RP160222	Rao, Hai	The University of Texas Helath Science Center at San Antonio	Carol Prives
RP160373	Naora, Honami	The University of Texas MD Anderson Cancer Center	Greene, Geoffrey
RP160395*	Lee, Min Gyu	The University of Texas MD Anderson Cancer Center	Belinksy, Steven
RP160535	Kang, Min	Texas Tech University Health Sciences Center	DeClerck, Yves
RP160567*	Zhang, Michael	The University of Texas at Dallas	Lowlor, Elizabeth
RP160168	Felini, Martha	University of North Texas Health Science Center at Fort Worth	Olshan, Andrew
RP160224	Schick, Vanessa	The University of Texas Health Science Center at Houston	Brandon, Thomas

Application ID	Applicant	Institution	Conflict Noted
RP160354*	Stingo, Francesco	The University of Texas MD Anderson Cancer Center	Barlow, William; Li, Christopher; Peterson, Gloria
RP160408*	Shen, Qiang	The University of Texas MD Anderson Cancer Center	Kumar, Nagi
RP160470	Valerio, Melissa	The University of Texas Health Science Center at Houston	Kushi, Lawrence
RP160499*	Minnix, Jennifer	The University of Texas MD Anderson Cancer Center	Brandon, Thomas; Schnoll, Robert
RP160527	Hanash, Samir	The University of Texas MD Anderson Cancer Center	Barlow, William; Li, Christopher; Mucci, Lorelei
RP160554	Bondy, Melissa	Baylor College of Medicine	Haiman, Christopher; Martinez, Maria
RP160587	Wetter, David	Rice University	Brandon, Thomas
RP160525*	Jiang, Ning	The University of Texas at Austin	Press, Oliver; Riddell, Stanley
RP160540	Reynolds, Charles	Texas Tech University Health Sciences Center	Grupp, Stephen; Kast, W. Martin;
RP160466	Yuan, Baohong	University of Texas at Arlington	Zinn, Kurt

De-Identified Overall Evaluation Scores

Individual Investigator Research Awards for Cancer in Children and Adolescents

Academic Research Cycle 16.1

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within the Individual Investigator Research Awards mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

This comprehensive list of Individual Investigator Research Awards de-identified application scores created for the purpose of this CEO affidavit packet combines the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not.

Application ID	Final Overall
	Evaluation Score
RP160237*	1.8
RP160487*	1.9
RP160190*	2.0
RP160249*	2.1
RP160022*	2.2
ga	2.8
gb	3.0
gc	3.3
gd	3.3
ge	3.3
gf	3.3
gg	3.4
gh	3.5
gi	3.6
gj	3.7
gk	3.7
gl	3.7
gm	4.0
gn	4.0
go	4.0
gp	4.0
gq	4.0
gr	4.1
gs	4.2
gt	4.3
gu	4.3

^{* =} Recommended for funding

Application ID	Final Overall Evaluation Score
gv	4.3
gw	4.3
gx	4.3
gy	4.3
gz	4.3
ha	4.7
hb	4.7
hc	4.7
hd	4.7
he	5.0
hf	5.0
hg	5.0
hh	5.3
hi	5.3
hj	5.7
hk	5.7
hl	6.0
hm	6.3

Final Overall Evaluation Scores and Rank Order Scores





Ludwig Institute for Cancer Research Ltd October 29, 2015

Richard D. Kolodner Ph.D.

Director, San Diego Branch

Head, Laboratory of Cancer Genetics San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

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Mr. Pete Geren

Oversight Committee Presiding Officer Cancer Prevention and Research Institute of Texas Via email to pgcprit@sidrichardson.org

Mr. Wayne R. Roberts Chief Executive Officer Cancer Prevention and Research Institute of Texas Via email to wroberts@cprit.state.tx.us

Dear Mr. Geren and Mr. Roberts,

In reviewing the list of recommended applications, we were made aware of one minor error in scoring. Application RP160268 was assigned a score of 2.6 in the list, and the actual score should be 2.7. This recommended application was initially placed in row 41 and now appears in row 44. The change of score is reflected in the attached revised list. This does not change the outcome of the SRC recommendation.

Sincerely yours,

Richard D. Kolodner, Ph.D.

Chair, CPRIT Scientific Review Council





Ludwig Institute for Cancer Research Ltd October 29, 2015

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Head, Laboratory of Cancer Genetics San Diego Branch

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Mr. Pete Geren Oversight Committee Presiding Officer Cancer Prevention and Research Institute of Texas Via email to pgcprit@sidrichardson.org

Mr. Wayne R. Roberts Chief Executive Officer Cancer Prevention and Research Institute of Texas Via email to wroberts@cprit.state.tx.us

Dear Mr. Geren and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for the Individual Investigator Research Awards (IIRA), Individual Investigator Research Awards for Computational Biology (IIRACB), Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA), Individual Investigator Research Awards for Prevention and Early Detection (IIRAP), Research Training Awards (RTA), and Research Training Awards - Renewal (RTA-R) grant mechanisms. The SRC met on Friday, October 23, 2015 to consider the applications recommended by the peer review panels following their meetings that were held September 29 - October 7, 2015. During the SRC discussion, it was determined that the success rates (percentage of the number recommended/number reviewed) for four panels were much higher than the rates for the other three panels and higher than the historical approval rates. It was suggested that these four panels reduce their success rates to fall in line with the other panels, and all chairs agreed to the scoring adjustments. This resulted in some applications not being recommended for grant awards that received scores equal to or more favorable than some applications that were recommended for grant awards. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded after adjustments were made based on success rates.

Recommended funding amounts and the overall evaluation score are stated for each grant application. The SRC accepted the recommendations of the peer review panels concerning adjustments to three grant applications. These adjustments with justifications are listed at the end of the list of recommended projects. The total amount for the applications recommended is \$62,761,270.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.





Sincerely yours,

Richard D. Kolodner, Ph.D.

Chair, CPRIT Scientific Review Council

Attachment

Rank	App ID	Organization/Company	Application Title	Award Amount	Mech.	Overall Score
Kank	App ID	* *		Amount		Score
	DD1 (0157	The University of Texas	Cancer Intervention and Prevention	Ф2 002 250	RTA-	1.0
1	RP160157	Southwestern Medical Center	Discoveries Program	\$3,993,250	Renewal	1.2
			Decoding Cellular Heterogeneity of			
2	RP160192	Baylor College of Medicine	Malignant Glioma	\$899,701	IIRA	1.3
			Protein Truncation Mutations in WIP1:			
3	RP160451	Baylor College of Medicine	Effects on Cancer and Hematopoiesis	\$900,000	IIRA	1.5
			Development of Therapeutics			
			Targeting Truncated Adenomatous			
			Polyposis Coli (APC) as a Novel			
		The University of Texas	Prevention and Intervention Strategy			
4	RP160180	Southwestern Medical Center	for Colorectal Cancer	\$900,000	IIRA	1.8
			A novel epigenetic reader as			
		The University of Texas M. D.	therapeutic target in MLL-translocated		IIRACC	
5*	RP160237	Anderson Cancer Center	pediatric leukemias	\$900,000	A	1.8
			Baylor College of Medicine			
			Comprehensive Cancer Training		RTA-	
6	RP160283	Baylor College of Medicine	Program	\$3,986,268	Renewal	1.9
		The University of Texas				
_		Health Science Center at San			IIRACC	
7	RP160487	Antonio	Cytokine signaling in Ewing sarcoma	\$1,200,000	A	1.9
			A Randomized Controlled Trial (RCT)			
			of Patient Navigation for Lung Cancer			
	DD1 60000	The University of Texas	Screening in an Urban Safety-Net	01.402 51 5	110 : 5	
8	RP160030	Southwestern Medical Center	System	\$1,492,616	IIRAP	1.9
			Promoting The Functions of Memory T			
9	RP160384	Baylor College of Medicine	cells for Adoptive T cell Therapy	\$887,676	IIRA	1.9
			Role of Long Non-Coding RNAs in			
			Breast Cancer: Identification,			
		The University of Texas	Characterization, and Determination of			
10	RP160318	Southwestern Medical Center	Molecular Functions	\$886,652	IIRA	2.0

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San Diego

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	T	I				
			Arylhydrocarbon receptor mediated			
11	RP160589	Texas AgriLife Research	modulation of colorectal cancer by microbiota metabolites	\$890,840	IIRAP	2.0
11	KI 100389	Texas Agrillic Research	Pediatric Radiation Oncology with	\$670,640	ШХЛ	2.0
		The University of Texas	Movie Induced Sedation Effect		IIRACC	
12**	RP160190	Southwestern Medical Center	(PROMISE)	\$900,000	A	2.0
		The University of Texas M. D.	Amplified gold nanoparticle-mediated			
13	RP160497	Anderson Cancer Center	radiosensitization of tumors	\$899,309	IIRA	2.0
			Imaging-based quantitative analysis of			
			vascular perfusion and tissue			
	DD1 (022)	The University of Texas M. D.	oxygenation to improve therapy of	#00 7 001	110.4	2 0
14	RP160229	Anderson Cancer Center	hepatocellular carcinoma Molecular Mechanism of NLRP12-	\$885,901	IIRA	2.0
		The University of Texas	mediated Regulation of Colorectal			
15	RP160169	Southwestern Medical Center	Cancer	\$897,707	IIRA	2.1
1.5	100107	The University of Texas	DIS3L2 in Childhood Wilms Tumor:	ΨΟΣ1,101	IIRACC	2,1
16***	RP160249	Southwestern Medical Center	Mechanism to Medicines	\$1,200,000	A	2.1
10	KI 100247	Southwestern Medicar Center	Carbamoyl Phosphate Synthase-1: A	\$1,200,000	A	2.1
		The University of Texas	new metabolic liability in non-small			
17	RP160089	Southwestern Medical Center	cell lung cancers	\$900,000	IIRA	2.1
		The Methodist Hospital	De-Orphanizing TLX: Implications for			
18	RP160501	Research Institute	Glioblastomas	\$878,969	IIRA	2.1
		The University of Texas				
19	RP160622	Southwestern Medical Center	Computational live cell histology	\$392,779	IIRACB	2.1
			Cancer Prevention Post-Graduate			
			Training Program in Integrative			
20	RP160097	Baylor College of Medicine	Epidemiology	\$2,986,890	RTA	2.1
		The University of Texas Health Science Center at	Collaborative Training of a New Cadre of Innovative Cancer Prevention		RTA-	
21	RP160015	Houston	Researchers	\$4,000,000	Renewal	2.1
21	KI 100013		The role of the Lats kinases in	\$4,000,000	Renewar	2.1
22	RP160340	The University of Texas Southwestern Medical Center	sarcomatoid renal cell carcinoma	\$899,598	IIRA	2.2
	X1 100340	Bouthwestern Medical Ceiller		φυ22,220	IIIVA	۷.۷
		The University of Taxas M. D.	Exploiting molecular and metabolic			
23	RP160183	The University of Texas M. D. Anderson Cancer Center	dependencies to optimize personalized therapeutic approaches for melanomas	\$900,000	IIRA	2.2
23	KI 100103	Anderson Cancer Center	Understanding Biological and Physical	\$300,000	IIIVA	4.4
			Factors Affecting Response to Proton			
		The University of Texas M. D.	Therapy to Improve its Clinical			
24	RP160232	Anderson Cancer Center	Effectiveness	\$879,362	IIRA	2.2
			Role of Cohesin in Hematopoiesis and			
			Myeloid Leukemia in Children with	** **********************************	IIRACC	
25	RP160022	Baylor College of Medicine	Down Syndrome	\$1,905,638	A	2.2
26	DD1 (02.42	The University of Texas M. D.	Mechanisms and targeting strategies for	#000	IID 4	2.2
26	RP160242	Anderson Cancer Center	SWI/SNF mutations in cancer	\$900,000	IIRA	2.3
		The University of Texas	Targeting the undruggable: a first-in- class inhibitor of the HIF-2			
27	RP160440	Southwestern Medical Center	transcription factor	\$899,412	IIRA	2.3
	111100770	Southwestern Moulear Center	manoriphon metor	Ψυλλ, Τ1Δ	1111/1	۵.5

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

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28	RP160145	The University of Texas M. D. Anderson Cancer Center	Early Detection of Ovarian Cancer with Tumor Associated Proteins and Autoantibodies	\$1,497,595	IIRAP	2.3
29	RP160013	The University of Texas M. D. Anderson Cancer Center	Visualizing T-cell trafficking	\$900,000	IIRA	2.3
30	RP160019	The University of Texas M. D. Anderson Cancer Center	An Adaptive Personalized Clinical Trial using a Patient-Derived Xenograft Strategy to Overcome Ibrutinib Resistance in Mantle Cell Lymphoma	\$841,606	IIRA	2.3
31	RP160051	Texas A&M University System Health Science Center	Improving contrast for antibody-based tumor detection using PET	\$887,134	IIRA	2.3
32	RP160023	The University of Texas M. D. Anderson Cancer Center	Investigating the genetic and molecular mechanisms underlying RAS/ERK substrate network Novel tumorigenic mechanisms of the	\$900,000	IIRA	2.4
33	RP160211	The University of Texas Southwestern Medical Center	LKB1 tumor suppressor in endometrial and cervical cancer	\$896,653	IIRA	2.4
34	RP160319	The University of Texas Southwestern Medical Center	Role of PARP-1 in Estrogen Receptor Enhancer Function and Gene Regulation Outcomes in Breast Cancers	\$884,315	IIRA	2.4
35	RP160124	The University of Texas Health Science Center at San Antonio	Chemoprevention of Colon Cancer by Anti-inflammatory Blockade Using Neem	\$899,617	IIRAP	2.4
36	RP160188	The University of Texas M. D. Anderson Cancer Center	Regulation of infiltration and function of tumor-resident CD8 T cells by IL-15	\$828,060	IIRA	2.4
37	RP160255	The University of Texas Southwestern Medical Center	Structural and Functional Analyses of the Spindle Checkpoint	\$900,000	IIRA	2.5
38	RP160307	The University of Texas Southwestern Medical Center	Targeting Metastatic Pathways	\$900,000	IIRA	2.5
39	RP160517	The University of Texas M. D. Anderson Cancer Center	Exosomal DNA as a surrogate biomarker for early diagnosis and therapeutic stratification in pancreatic cancer	\$891,938	IIRA	2.5
40	RP160345	Baylor College of Medicine	Engineering T cells to ensure specificity for tumor cells and their environment	\$900,000	IIRA	2.5
41	RP160482	The University of Texas M. D. Anderson Cancer Center	Nanoparticle Targeted STAT3 Immune Expression Clinical Safety and Efficacy of Third	\$888,429	IIRA	2.6
42	RP160121	The University of Texas M. D. Anderson Cancer Center	party, fucosylated, cord blood derived regulatory T cells to prevent graft versus host disease	\$900,000	IIRA	2.6
43	RP160520	The University of Texas Southwestern Medical Center	Effect of Chest Radiation Therapy on Cardiomyocyte Turnover	\$897,570	IIRAP	2.6
44	RP160268	The University of Texas Southwestern Medical Center	DNA damage-induced small non- coding RNAs: mechanism and their role in cancer development	\$900,000	IIRA	2.7

LUDWIG CANCER RESEARCH

San Diego

ludwigcancerresearch.org

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			Integrin-mediated IL-18 signaling in			
		The University of Texas	the prevention and treatment of			
		Health Science Center at San	inflammation-associated colorectal			
45	RP160512	Antonio	cancer	\$859,620	IIRA	2.7
			A novel function of Itch in controlling			
			IL-17-induced inflammation in colon			
46	RP160577	Baylor Research Institute	cancer	\$900,000	IIRA	2.7
			Optimizing therapeutic strategies			
		The University of Texas at	against lung cancer using Multi-			
47	RP160617	Dallas	Modality Imaging	\$899,999	IIRA	2.7
			Characterization and pharmacological			
		The University of Texas	targeting of the oncogenic activity of			
48	RP160493	Southwestern Medical Center	Jumonji enzymes	\$899,997	IIRA	2.8
			The CTC Circulator Phenotype:	Í		
			Insights into Mechanisms of Breast			
49	RP160054	Baylor College of Medicine	Cancer Dormancy	\$884,332	IIRA	2.9
49	KF 100034	The University of Texas	Regulation of tumor aggressiveness and	\$664,332	IIKA	2.9
		Health Science Center at	immune suppression in lung			
50	DD160225		adenocarcinoma	000 000	IID A	2.0
50	RP160235	Houston	1	\$900,000	IIRA	2.9
			Radiogenomic Screen to Identify Novel			
			Proliferation-associated Glioblastoma			
			Genomic Therapeutic Targets:			
5.1	DD1 601 50	The University of Texas M. D.	Discovery and Mechanistic Validation	#00 7.637	IID 4	2.0
51	RP160150	Anderson Cancer Center	Study	\$897,627	IIRA	3.0
			High resolution imaging for early and			
52	RP160460	Rice University	better detection of bladder cancer	\$873,765	IIRAP	3.0
		The University of Texas M. D.	Identifying new epigenetic	·		
53	RP160471	Anderson Cancer Center	vulnerabilities in pancreatic cancer	\$900,000	IIRA	3.1
- 55	10 100 1/1	- Indiana Canton Conton	Systematic identification of small	Ψ>00,000	111(/ 1	5.1
			molecule inhibitors that manipulate			
54	RP160462	Baylor College of Medicine	telomerase activities	\$898,288	IIRA	3.2
J-T	100402	Buylor Conege of Wicdichie	The role of Prdm16 and histone H3	\$676,266	шил	J.L
			lysine 9 methyltransferase complex in			
55	RP160035	Baylor College of Medicine	MDS	\$872,157	IIRA	3.2
33	KI 100033	Daylor College of Medicille	MIDS	\$6/2,13/	ШЛА	3.4

^{*}RP160237 - The peer review panel recommended reducing the budget to \$300,000 per year for 3 years for a total of \$900,000 based on the scope and depth of the work proposed.

^{**}RP160190 - The peer review panel recommended not funding Aim 4 (Pilot prospective clinical trial) and reducing the budget to \$300,000 per year for 3 years for a total of \$900,000. The final score was based on revised scope with full deletion of Aim 4.

^{***}RP160249 - The peer review panel recommended that given the absence of a clinical trial, the budget should be reduced to \$300,000 per year for 4 years for a total of \$1,200,000.





Success Rate by Panel			
Peer Review	Success	Score	
Panel	Rate	Cutoff	
BCR1	10%	2.3	
BCR2	11%	3.2	
СВ	9%	3.2	
CPR	9%	2.4	
CTCR/TCR	13%	2.7	
ITI	11%	3.0	

Success Rate by Mechanism vs. Total Reviewed					
Mechanism	Success Rate	# Recommended			
IIRA	11%	39/347			
IIRACB	2%	1/50			
IIRACCA	11%	5/44			
IIRAP	13%	6/44			
RTA	14%	1/7			
RTA-R	50%	3/6			
Overall	11%	55/498			

Percent of Applications Recommended by			
Mechanism vs. Total Recommended			
Mechanism	# Recommended	Percentage	
IIRA	39/55	71%	
IIRACB	1/55	2%	
IIRACCA	5/55	9%	
IIRAP	6/55	11%	
RTA	1/55	2%	
RTA-R	3/55	5%	
Overall	55/55	100%	



CEO Affidavit Supporting Information

FY 2016—Cycle 1
Individual Investigator Research Awards
for Prevention and Early Detection

Request for Applications



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS RFA R-16-IIRAP-1

Individual Investigator Research Awards for Prevention and Early Detection

Please also refer to the Instructions for Applicants document, which will be posted on March 20, 2015

Application Receipt Opening Date: March 20, 2015 **Application Receipt Closing Date:** May 20, 2015

FY 2016

Fiscal Year Award Period September 1, 2015-August 31, 2016

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RFA VERSION HISTORY

Rev 02/20/15 RFA release

1. ABOUT CPRIT

The state of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the
 potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the state of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The principles and priorities of the Scientific Research program will guide CPRIT staff, peer reviewers, and the Scientific Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs. The program priorities for research adopted by the Oversight Committee include funding projects that address:

- A broad range of innovative, investigator-initiated research projects;
- Prevention and early detection;
- Rare and intractable cancers, including childhood cancers;
- Cancers of importance in Texas;
- Computational biology and analytic methods; and
- Building Infrastructure.

2. RATIONALE

A major opportunity for investment in cancer research is in the area of cancer prevention.

Nowhere is there greater potential to reduce the burden of cancer than by reducing its incidence.

This has the added advantage of sparing people and families from the psychological and emotional trauma of a cancer diagnosis, the often devastating physical consequences of cancer

therapies, and the financial burdens associated with cancer treatment. Identification of causes of cancer, including environmental chemicals, microbial agents, and genetic susceptibilities, is essential for reducing cancer incidence. In addition, intervening in the process at early stages of cancer development, before genetic instability becomes widespread, holds promise of successfully eliminating cells destined to become cancer cells. Basic research on the identification and control of premalignant cells, the role of the tumor cell microenvironment in tumor development, environmental drivers, and predictive markers of cancer progression from normal to neoplastic may provide new avenues for intervening early in the process of cancer development. Early detection of cancer using biomarkers and early screening methods also can reduce morbidity and mortality from cancer. Although CPRIT is required to spend 10% of its budget on cancer prevention, CPRIT's Cancer Prevention Program focuses exclusively on the delivery of evidence-based interventions to underserved populations and does not fund prevention research.

Thus, there is a unique opportunity for CPRIT's Research Program to fund research on adoption of cancer-preventing behaviors, effectiveness of various interventions, and how best to deliver prevention services that could eventually result in implementation through the Prevention Program.

3. RESEARCH OBJECTIVES

This Request for Applications (RFA) solicits applications for innovative research projects addressing questions that will advance current knowledge of the causes, prevention, early-stage progression from normal to neoplastic cells, and/or early detection of cancer. Applications may address any topic or issue related to cancer causation, prevention, early progression, or early detection. Research may be laboratory-, clinical-, or population-based and may include behavioral/intervention, dissemination, or health services/outcomes research to reduce cancer incidence or promote early detection. CPRIT expects the outcomes of activities supported by this mechanism to reduce the burden of cancer in the near or long term. CPRIT encourages applications that seek to apply or develop state-of-the-art technologies, tools, and/or resources for prevention or early detection of cancer, including those with potential commercialization opportunities. Successful applicants should be working in a research environment capable of supporting potentially high-impact studies. Partnering with cancer biologists or oncologists is highly recommended for Principal Investigators (PIs) who do not have this expertise.

The subject of applications may include, but is not limited to, the following:

- Environmental carcinogenesis, including high-throughput methods for carcinogen detection and identification of carcinogens and their mechanisms of action
- Role of microbial agents in cancer causation
- Cancer epidemiology
- Identification of populations at high risk of developing cancer
- Cellular and molecular alterations leading to development of precancerous lesions
- Approaches to prevent progression of normal to preneoplastic cells to cancer cells
- Methods for early detection of cancer
- Development and testing of intervention strategies to increase access to and improve recently endorsed screening technologies for cancer
- Cancer-focused health services/outcomes or patient-centered outcomes research
- Development and adaptation of novel interventions for effective and efficient delivery of cancer prevention and screening services

The *degree of relevance* to reducing the burden of cancer will be an important criterion for evaluation of projects for funding by CPRIT.

4. FUNDING INFORMATION

Applicants may request a maximum of \$300,000 in total costs per year for up to 3 years for laboratory and clinical research and up to \$500,000 in total costs per year for up to 3 years for population-based research. Exceptions to these limits may be requested if extremely well justified (see section 8.2.10). Applications funded in this cycle will be eligible for competitive renewal. Funds may be used for salary and fringe benefits, research supplies, equipment, subject participation costs, and travel to scientific/technical meetings or collaborating institutions. Requests for funds to support construction and/or renovation will not be approved under this funding mechanism. State law limits the amount of award funding that may be spent on indirect costs to no more than 5% of the total award amount.

5. ELIGIBILITY

• The applicant must be a Texas-based entity. Any not-for-profit institution or organization that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism; these

- entities must use the appropriate award mechanism(s) under CPRIT's Product Development Program.
- The PI must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM,
 or equivalent, and must reside in Texas during the time the research that is the subject of
 the grant is conducted.
- A PI may submit only 1 new application under this RFA during this funding cycle. A PI may not submit applications to this RFA and to RFA R-16-IIRA-1, RFA R-16-IIRACCA-1, or RFA R-16-IIRACB-1. Only 1 IIRAP, IIRA, IIRACB, or IIRACCA application per cycle is allowed. An investigator who is the PI on 3 or more CPRIT grants of any type that will be active December 1, 2015 is not eligible to submit an application in response to this RFA.
- Applications that address untargeted research, Cancers in Children and Adolescents, or Computational Biology should be submitted under the appropriate targeted RFA.
- Because this award mechanism is intended to support research directed by a single investigator, only 1 Co-PI may be included. Collaborators should have specific and welldefined roles.
- Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the state of Texas, but non—Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PI, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the PI, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant

- funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. RESUBMISSION POLICY

An application previously submitted to CPRIT but not funded may be resubmitted once and must follow all resubmission guidelines. More than 1 resubmission is not permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PI for a project or a change of title of the project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission. This policy is in effect for all applications submitted to date. See section 8.2.5.

7. RENEWAL POLICY

An application originally funded by CPRIT as an IIRA that is appropriate for the IIRAP mechanism may be submitted under this RFA for a competitive renewal. See <u>section 8.2.6</u>. Competitive renewals are not subject to preliminary evaluation. Renewal applications move directly to the full peer review phase. See <u>section 9.2</u>.

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and submit an application. The Co-PI, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing

Official (ASO) (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on March 20, 2015, and must be submitted by 3 PM central time on May 20, 2015. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

8.1.1. Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via email to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in <u>section 5</u> will be administratively withdrawn without review.

8.2.1. Abstract and Significance (5,000 characters)

Clearly explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the Research Plan. Clearly address how the proposed project, if successful, will have a major impact on cancer. Summarize how the proposed research creates new paradigms or challenges existing ones. Indicate whether this research plan represents a new direction for the PI.

Note: It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance statement alone. Therefore, applicants are advised to prepare this section wisely. Applicants should not waste this valuable space by stating obvious facts (eg, that cancer is a significant problem; that better diagnostic and therapeutic approaches are needed urgently; that the type of cancer of interest to the PI is important, vexing, or deadly). Based on this statement (and the Budget and Justification and Biographical Sketches), applications that are judged to offer only modest contributions to the field of cancer research or that do

not sufficiently capture the reviewers' interest may be excluded from further peer review (see section 9.1).

8.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer research, early diagnosis, prevention, or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Do not include any proprietary information in the Layperson's Summary. The Layperson's Summary will also be used by advocate reviewers (section 9.2) in evaluating the significance and impact of the proposed work.

8.2.3. Goals and Objectives

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success.

8.2.4. Timeline (1 page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.5. Resubmission Summary (1 page)

Applicants preparing a resubmission must describe the approach to the resubmission. If a summary statement was prepared for the original application review, applicants are advised to address all noted concerns.

Note: An application previously submitted to CPRIT but not funded may be resubmitted once after careful consideration of the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a fresh Research Plan or modify the original Research Plan and mark the changes. However, all resubmitted applications should be carefully reconstructed; a simple revision of the

prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

8.2.6. Renewal Summary (2 pages)

Applicants preparing a renewal must describe and demonstrate that appropriate/adequate progress has been made on the current funded award to warrant further funding. Publications and manuscripts in press that have resulted from work performed during the initial funded period should be listed in the renewal summary.

8.2.7. Research Plan (10 pages)

Background: Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed.

Hypothesis and Specific Aims: Concisely state the hypothesis and/or specific aims to be tested or addressed by the research described in the application.

Research Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data that support the proposed hypothesis are encouraged but not required.

8.2.8. Vertebrate Animals and/or Human Subjects (1 page)

If vertebrate animals will be used, provide an outline of the appropriate protocols that will be followed. If human subjects or human biological samples will be used, provide a plan for recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism.

8.2.9. Publications/References

Provide a concise and relevant list of publications/references cited for the application.

8.2.10. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. Do not exceed \$300,000 per year for laboratory and clinical studies, and \$500,000 for population-based studies. Applicants are advised not to interpret the maximum allowable request under this award as a suggestion that they should expand their anticipated budget to this level. Reasonable budgets clearly work in favor of the applicant.

However, if there is a highly specific and defensible need to request more than the maximum amount in any year(s) of the proposed budget, include a special and clearly labeled section in the budget justification that explains the request. Poorly justified requests of this type will likely have a negative impact on the overall evaluation of the application.

In preparing the requested budget, applicants should be aware of the following:

- Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. So-called grants management and facilities fees (eg, sponsored programs fees; grants and contracts fees; electricity, gas, and water; custodial fees; maintenance fees) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.
- The annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2016 is \$200,000; CPRIT FY 2016 is from September 1, 2015, through August 31, 2016. Salary does not include fringe benefits and/or facilities and administrative (F&A) costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

8.2.11. Biographical Sketches (2 pages each)

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. A biographical sketch must be provided for the PI and, if applicable, the Co-PI (as required by the online application receipt system). Up to 2 additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed 2 pages.

8.2.12. Current and Pending Support

Describe the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title, a 2-line summary of the goal of the project and, if relevant, a statement of overlap with the current application. At a minimum, current and pending support of the PI and, if applicable, the Co-PI must be provided.

8.2.13. Institutional/Collaborator Support and/or Other Certification (4 pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of 4 pages may be provided.

8.2.14. Previous Summary Statement

If the application is being resubmitted, the summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission. The applicant is not responsible for providing this document.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively rejected without review.

9. APPLICATION REVIEW

9.1. Preliminary Evaluation

To ensure the timely and thorough review of only the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, all eligible applications may be preliminarily evaluated by CPRIT Scientific Research Program panel members for scientific merit and impact.

This preliminary evaluation will be based on a subset of material presented in the application—namely Abstract and Significance, Budget and Justification, and Biographical Sketches. Applications that do not sufficiently capture the reviewers' interest at this stage will not be considered for further review. Such applications will have been judged to offer only modest contributions to the field of cancer research and will be excluded from further peer review.

The applicant will be notified of the decision to disapprove the application after the preliminary evaluation stage has concluded. Due to the volume of applications to be reviewed, comments made by reviewers at the preliminary evaluation stage may not be provided to applicants. The preliminary evaluation process will be used only when the number of applications exceeds the capacity of the review panels to conduct a full peer review of all received applications.

9.2. Full Peer Review

Applications that pass preliminary evaluation will undergo further review using a 2-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts as well as advocate reviewers using the criteria listed below. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by Scientific Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

9.3. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Peer Review Panel members and Scientific Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee Member, a PIC Member, a Scientific Review Panel member, or a Scientific Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

9.4. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.

9.4.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study. Primary criteria include the following:

Significance and Impact: Will the results of this research, if successful, significantly change the research of others or the opportunities for better cancer prevention, diagnosis, or treatment for patients? Is the application innovative? Does the applicant propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important underexplored or unexplored areas? If the research project is successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? Projects that modestly extend current lines of research will not be considered for this award. Projects that represent straightforward extensions of ongoing work, especially work traditionally funded by other mechanisms, will not be competitive.

Research Plan: Is the proposed work presented as a self-contained research project? Does the proposed research have a clearly defined hypothesis or goal that is supported by sufficient preliminary data and/or scientific rationale? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed?

Applicant Investigator: Does the applicant investigator demonstrate the required creativity and expertise to make a significant contribution to the research? Applicants' credentials will be evaluated in a career stage—specific fashion. Have early career—stage investigators received excellent training, and do their accomplishments to date offer great promise for a successful career? Has the applicant devoted a sufficient amount of his or her time (percentage effort) to this project?

Relevance: Does the proposed research have a high degree of relevance to cancer prevention research or early detection? This will be an important criterion for evaluation of projects for CPRIT support.

9.4.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed research.

Secondary criteria include the following:

Research Environment: Does the research team have the needed expertise, facilities, and resources to accomplish all aspects of the proposed research? Are the levels of effort of the key personnel appropriate? Is there evidence of institutional support of the research team and the project?

Vertebrate Animals and/or Human Subjects: If vertebrate animals and/or human subjects are included in the proposed research, certification of approval by the institutional IACUC and/or IRB, as appropriate, will be required before funding can occur.

Budget: Is the budget appropriate for the proposed work?

Duration: Is the stated duration appropriate for the proposed work?

10. KEY DATES

RFA

RFA release February 20, 2015

Application

Online application opens March 20, 2015, 7 AM central time

Application due May 20, 2015, 3 PM central time

Application review September - October 2015

Award

Award notification November 2015

Anticipated start date March 2016

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. Applicants are advised to review CPRIT's administrative rules related to

contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed, and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements regarding demonstration of available funding.

13. CONTACT INFORMATION

13.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding scientific aspects of applications.

Dates of operation: February 20 – May 20, 2015 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time

Wednesday, 8 AM to 4 PM central time

Tel: 866-941-7146

Email: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Senior Manager for Research.

Tel: 512-305-8491

Email: Help@CPRITGrants.org

Website: www.cprit.state.tx.us

Third Party Observer Reports



CPRIT Research Peer Review Observation Report

Report #2015-09-29-RES

Program Name: Academic Research

Panel Name: FY16.1 Clinical & Translational Cancer

Research and Translational Cancer Research

Panel Date: September 29, 2015 Report Date: October 7, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Clinical & Translational Cancer Research and Translational Cancer Research peer review of applications for FY16 funding. The meeting was co-chaired by Richard O'Reilly and Margaret Tempero and held at the Marriott Suites Medical/Market Center in Dallas TX on September 29, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Clinical & Translational Cancer Research and Translational Cancer Research panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and co-chaired by Richard O'Reilly and Margaret Tempero on September 29, 2015.

The independent observer noted the following during our observation:

- Twenty-four applications were discussed within the Research Peer Review Meeting to determine which
 grants would receive CPRIT funding.
- Twenty-six peer review panelists, three advocate reviewers, three CPRIT staff members and five SRA employees were present for the meeting.
 - o Two of the twenty-six peer review panelists participated via teleconference.
- Thirteen conflicts of interest were identified prior to or during the meeting. Applications for nine
 conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest either
 left the room or did not participate telephonically and did not participate in the review of the conflicted
 application.
 - One of the nine conflicts did not sign out on the conflict of interest sign out sheet when leaving the room.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Research Peer Review Observation Report

Report #2015-09-30-RES

Program Name: Academic Research

Panel Name: FY16.1 Cancer Prevention Research

Panel Date: September 30, 2015 Report Date: October 7, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Cancer Prevention Research peer review of applications for FY16 funding. The meeting was chaired by Tom Sellers and held at the Marriott Suites Medical/Market Center in Dallas TX on September 30, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Cancer Prevention Research panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Tom Sellers on September 30, 2015.

The independent observer noted the following during our observation:

- Nineteen applications were discussed within the Research Peer Review Meeting to determine which
 grants would receive CPRIT funding.
- Seventeen peer review panelists, two advocate reviewers, four CPRIT staff members and five SRA
 employees were present for the meeting.
 - One of the seventeen peer review panelists participated via teleconference and for only one application.
- Twenty-one conflicts of interest were identified prior to or during the meeting. Applications for fifteen
 conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest either
 left the room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical
or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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CPRIT Research Peer Review Observation Report

Report #2015-10-01-RES

Program Name: Academic Research

Panel Name: FY16.1 Imaging Technology and

Informatics

Panel Date: October 1, 2015 Report Date: October 7, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Imaging Technology and Informatics peer review of applications for FY16 funding. The meeting was chaired by Sam Gambhir and held at the Marriott Suites Medical/Market Center in Dallas TX on October 1, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Imaging Technology and Informatics panel meeting held inperson. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Sam Gambhir on October 1, 2015.

The independent observer noted the following during our observation:

- Eighteen applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Twenty-one peer review panelists, two advocate reviewers, two CPRIT staff members and five SRA
 employees were present for the meeting.
 - One of the twenty-one peer review panelists participated via teleconference.
- Five conflicts of interest were identified prior to or during the meeting. Applications for two conflicts
 were discussed during the peer review panel. The reviewers with the conflicts of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Research Peer Review Observation Report

Report #2015-10-05-RES

Program Name: Academic Research

Panel Name: FY16.1 Basic Cancer Research 2

Panel Date: October 5, 2015 Report Date: October 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Basic Cancer Research 2 peer review of applications for FY16 funding. The meeting was chaired by Carol Prives and held at the Marriott Suites Medical/Market Center in Dallas TX on October 5, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Basic Cancer Research 2 panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Carol Prives on October 5, 2015.

The independent observer noted the following during our observation:

- Nineteen applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Fifteen peer review panelists, two advocate reviewers, two CPRIT staff members, five SRA employees
 and chair for the Scientific Review Council were present for the meeting.
 - o Two of the fifteen peer review panelists participated via teleconference.
 - One participated for review of only four applications and the other participated as an ad hoc reviewer for one application.
- Two conflicts of interest were identified prior to or during the meeting. Applications for one conflict
 was discussed during the peer review panel. The reviewer with the conflict of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
 - o The reviewer was present when final scores were still visible on projection screen.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Research Peer Review Observation Report

Report #2015-10-06-RES

Program Name: Academic Research

Panel Name: FY16.1 Basic Cancer Research 1

Panel Date: October 6, 2015 Report Date: October 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Basic Cancer Research 1 peer review of applications for FY16 funding. The meeting was chaired by Tom Curran and held at the Marriott Suites Medical/Market Center in Dallas TX on October 6, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Basic Cancer Research 1 panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Tom Curran on October 6, 2015.

The independent observer noted the following during our observation:

- Thirty applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Eighteen peer review panelists, two advocate reviewers, three CPRIT staff members and six SRA
 employees were present for the meeting.
 - One of the eighteen peer review panelists participated via teleconference.
 - One of the two advocate reviewers participated via teleconference.
- Two conflicts of interest were identified prior to or during the meeting. Applications for one conflict
 was discussed during the peer review panel. The reviewer with the conflict of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical
or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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CPRIT Research Peer Review Observation Report

Report #2015-10-07-RES

Program Name: Academic Research

Panel Name: FY16.1 Cancer Biology

Panel Date: October 7, 2015 Report Date: October 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Cancer Biology peer review of applications for FY16 funding. The meeting was chaired by Peter Jones and held at the Marriott Suites Medical/Market Center in Dallas TX on October 7, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Cancer Biology panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Peter Jones on October 7, 2015.

The independent observer noted the following during our observation:

- Twenty-two applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Fifteen peer review panelists, two advocate reviewers, two CPRIT staff members and five SRA
 employees were present for the meeting.
 - o Two of the fifteen peer review panelists participated via teleconference.
- Seven conflicts of interest were identified prior to or during the meeting. Applications for five conflicts
 were discussed during the peer review panel. The reviewers with the conflicts of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Scientific Review Council Meeting Observation Report

Report #2015-10-23-RES

Program Name: Academic Research

Panel Name: FY16.1 Scientific Review Council

Meeting

Panel Date: October 23, 2015 Report Date: October 27, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Scientific Review Council Meeting peer review of applications for FY16 funding. The meeting was chaired by Richard Kolodner and held via teleconference on October 23, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Scientific Review Council Meeting held via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Richard Kolodner on October 23, 2015.

The independent observer noted the following during our observation:

- Over the course of the call, a review of the scoring for the 65 recommended applications was completed to ensure that they would in fact be recommended for funding. A score cut-off was reinforced by the panel as to which applications will move forward.
- Six peer review panelists, two CPRIT staff members and one SRA employee were present for the meeting.
- No conflicts of interest were identified prior to or during the meeting.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Academic Research Cycle 16.1 Applications (Academic Research Cycle 16.1 Awards Announced at November 19, 2015 Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Cycle 16.1 include Individual Investigator Research Awards, Individual Investigator Research Awards for Prevention and Early Detection, Individual Investigator Research Awards for Cancer in Children and Adolescents, Individual Investigator Research Awards for Computational Biology, and Research Training Awards. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
RP160183pe/ RP160183	Davies, Michael	The University of Texas M. D. Anderson Cancer Center	McMahon, Martin
RP160471pe/ RP160471	Draetta, Giulio	The University of Texas M. D. Anderson Cancer Center	Courtneidge, Sara
RP160013pe/ RP160013	Kundra, Vikas	The University of Texas M. D. Anderson Cancer Center	Riddell, Stanley; Engelhard, Victor
RP160188pe/ RP160188	Schluns, Kimberly	The University of Texas M. D. Anderson Cancer Center	Engelhard, Victor
RP160482pe/ RP160482	Heimberger, Amy	The University of Texas M. D. Anderson Cancer Center	Engelhard, Victor
RP160577pe/ RP160577	Poojary, Venuprasad	Baylor Research Institute	Cooney, Kathleen
RP160497pe/ RP160497	Krishnan, Sunil	The University of Texas M. D. Anderson Cancer Center	Berbeco, Ross
RP160589	Chapkin, Robert	Texas AgriLife Research	Fearon, Eric; Greene, Geoffrey

Application ID Applicant Institution Conflic	ct Noted
RP160015 Ness, Roberta The University of Texas Haiman, C	Christopher;
Health Science Center at Kushi, Lav	1 /
Houston Rushi, Eav	Wichee
RP160030 Gerber, David The University of Texas Barlow, W	/illiam
Southwestern Medical	, 11114111
Center	
RP160097 Spitz, Margaret Baylor College of Martinez,	Maria
Medicine	
RP160145 Bast, Robert The University of Texas Kushi, Lav	wrence; Li,
MD Anderson Cancer Christophe	
Center	
Applications Not Recommended for PIC or Oversight Committee Consid	leration
RP160117pe/ Chen, Benjamin The University of Texas Bart Willia	ams
RP160117* Southwestern Medical	
Center	
RP160472pe Cox, Marc The University of Texas McMahon	, Martin
at El Paso	
RP160079pe Saikumar, Pothana The University of Texas Sonenberg	g, Nahum
Health Science Center at	
San Antonio	
RP160113pe Davis, Anthony The University of Texas Tomkinson	
Southwestern Medical Chazin, W	/alter
Center	
RP160304pe Denicourt, Catherine The University of Texas Petrini, John March 1988 Petrini, Petri	hn
Health Science Center at	
RP160335pe/ Wang, Bin Houston The University of Texas Matthew V	Waitzman
RP160335pe/ Wang, Bin The University of Texas Matthew V M. D. Anderson Cancer	w enzman
Center	
RP160374pe Boothman, David The University of Texas Tomkinson	n Alan
Southwestern Medical	ii, Maii
Center	
RP160611pe Schiff, Rachel Baylor College of Petrini, Jol	hn
Medicine	
RP160621pe Latham, Michael Texas Tech University Petrini, Jol	hn
RP160506pe Aiden, Erez Baylor College of Bernstein,	
Medicine Hahn, Wil	liam
RP160537pe Kim, Min The Methodist Hospital Wahl, Geo	offrey
Research Institute	
RP160477pe Hassan, Manal The University of Texas Petersen, C	
M. D. Anderson Cancer Martinez,	Maria
Center	

Application ID	Applicant	Institution	Conflict Noted
RP160076pe	Jha, Mithilesh	The University of Texas Health Science Center at San Antonio	Hochster, Howard
RP160143pe/ RP160143	Nurieva, Roza	The University of Texas M. D. Anderson Cancer Center	Stadler, Walter; Engelhard, Victor
RP160176pe/ RP160176*	Sharma, Padmanee	The University of Texas M. D. Anderson Cancer Center	Riddell, Stanley
RP160230pe	Trippier, Paul	Texas Tech University Health Sciences Center	Balk, Steven
RP160336pe/ RP160336*	Diab, Adi	The University of Texas M. D. Anderson Cancer Center	Engelhard, Victor
RP160359pe	Bhattacharya, Pratip	The University of Texas M. D. Anderson Cancer Center	Haas-Kogan, Daphne
RP160580pe	Biros, George	The University of Texas at Austin	Mitchell, Duane
RP160645pe/ RP160645*	Jo, Javier	Texas Engineering Experiment Station	Liu, Jonathan; Sutcliffe, Julie
RP160648pe/ RP160648*	Chen, Wei	The University of Texas at Arlington	Zinn, Kurt
RP160222	Rao, Hai	The University of Texas Helath Science Center at San Antonio	Carol Prives
RP160373	Naora, Honami	The University of Texas MD Anderson Cancer Center	Greene, Geoffrey
RP160395*	Lee, Min Gyu	The University of Texas MD Anderson Cancer Center	Belinksy, Steven
RP160535	Kang, Min	Texas Tech University Health Sciences Center	DeClerck, Yves
RP160567*	Zhang, Michael	The University of Texas at Dallas	Lowlor, Elizabeth
RP160168	Felini, Martha	University of North Texas Health Science Center at Fort Worth	Olshan, Andrew
RP160224	Schick, Vanessa	The University of Texas Health Science Center at Houston	Brandon, Thomas

Application ID	Applicant	Institution	Conflict Noted
RP160354*	Stingo, Francesco	The University of Texas MD Anderson Cancer Center	Barlow, William; Li, Christopher; Peterson, Gloria
RP160408*	Shen, Qiang	The University of Texas MD Anderson Cancer Center	Kumar, Nagi
RP160470	Valerio, Melissa	The University of Texas Health Science Center at Houston	Kushi, Lawrence
RP160499*	Minnix, Jennifer	The University of Texas MD Anderson Cancer Center	Brandon, Thomas; Schnoll, Robert
RP160527	Hanash, Samir	The University of Texas MD Anderson Cancer Center	Barlow, William; Li, Christopher; Mucci, Lorelei
RP160554	Bondy, Melissa	Baylor College of Medicine	Haiman, Christopher; Martinez, Maria
RP160587	Wetter, David	Rice University	Brandon, Thomas
RP160525*	Jiang, Ning	The University of Texas at Austin	Press, Oliver; Riddell, Stanley
RP160540	Reynolds, Charles	Texas Tech University Health Sciences Center	Grupp, Stephen; Kast, W. Martin;
RP160466	Yuan, Baohong	University of Texas at Arlington	Zinn, Kurt

High Level Summary of Due Diligence

De-Identified Overall Evaluation Scores

Individual Investigator Research Awards for Prevention and Early Detection

Academic Research Cycle 16.1

See the "Final Overall Evaluation Scores and Rank Order Scores" section for an explanation of the Scientific Review Council's review and recommendation of grant awards.

Application ID	Final Overall
RP160030*	Evaluation Score
RP160030*	1.9 2.0
RP160589*	
	2.3
RP160124*	2.4
ia	2.5
RP160520*	2.6
ib	3.0
RP160460*	3.0
ic	3.3
id	3.3
ie	3.3
if	3.4
ig	3.5
ih	3.7
ii	3.7
ij	3.7
ik	3.8
il	3.8
im	3.8
in	4
io	4.3
ip	4.3
iq	4.3
ir	4.7
is	4.7
it	4.7
iu	4.7
iv	4.7
iw	4.8
ix	5.0
iy	5.0
iz	5.0
ja	5.0
jb	5.3
jc	5.3
jd	5.3

^{*=}Recommended for funding

Application ID	Final Overall Evaluation Score
je	5.3
jf	5.3
jg	5.7
jh	5.7
ji	6.7
jj	6.7
jk	6.7
jl	7.7

Final Overall Evaluation Scores and Rank Order Scores





San Diego

Ludwig Institute for Cancer Research Ltd October 29, 2015

Richard D. Kolodner Ph.D.

Director, San Diego Branch

Head, Laboratory of Cancer Genetics San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

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UC San Diego School of Medicine CMM-East / Rm 3058 9500 Gilman Dr - MC 0669 La Jolla, CA 92093-0669

T 858 534 7804 **F** 858 534 7750

Mr. Pete Geren

Oversight Committee Presiding Officer Cancer Prevention and Research Institute of Texas Via email to pgcprit@sidrichardson.org

Mr. Wayne R. Roberts Chief Executive Officer Cancer Prevention and Research Institute of Texas Via email to wroberts@cprit.state.tx.us

Dear Mr. Geren and Mr. Roberts,

In reviewing the list of recommended applications, we were made aware of one minor error in scoring. Application RP160268 was assigned a score of 2.6 in the list, and the actual score should be 2.7. This recommended application was initially placed in row 41 and now appears in row 44. The change of score is reflected in the attached revised list. This does not change the outcome of the SRC recommendation.

Sincerely yours,

Richard D. Kolodner, Ph.D.

Chair, CPRIT Scientific Review Council





San Diego

Ludwig Institute for Cancer Research Ltd October 29, 2015

Richard D. Kolodner Ph.D.

Director, San Diego Branch

Head, Laboratory of Cancer Genetics San Diego Branch

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Mr. Pete Geren Oversight Committee Presiding Officer Cancer Prevention and Research Institute of Texas Via email to pgcprit@sidrichardson.org

Mr. Wayne R. Roberts Chief Executive Officer Cancer Prevention and Research Institute of Texas Via email to wroberts@cprit.state.tx.us

Dear Mr. Geren and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for the Individual Investigator Research Awards (IIRA), Individual Investigator Research Awards for Computational Biology (IIRACB), Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA), Individual Investigator Research Awards for Prevention and Early Detection (IIRAP), Research Training Awards (RTA), and Research Training Awards - Renewal (RTA-R) grant mechanisms. The SRC met on Friday, October 23, 2015 to consider the applications recommended by the peer review panels following their meetings that were held September 29 - October 7, 2015. During the SRC discussion, it was determined that the success rates (percentage of the number recommended/number reviewed) for four panels were much higher than the rates for the other three panels and higher than the historical approval rates. It was suggested that these four panels reduce their success rates to fall in line with the other panels, and all chairs agreed to the scoring adjustments. This resulted in some applications not being recommended for grant awards that received scores equal to or more favorable than some applications that were recommended for grant awards. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded after adjustments were made based on success rates.

Recommended funding amounts and the overall evaluation score are stated for each grant application. The SRC accepted the recommendations of the peer review panels concerning adjustments to three grant applications. These adjustments with justifications are listed at the end of the list of recommended projects. The total amount for the applications recommended is \$62,761,270.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.





San Diego

Sincerely yours,

Richard D. Kolodner, Ph.D.

Chair, CPRIT Scientific Review Council

Attachment

Rank	App ID	Organization/Company	Application Title	Award Amount	Mech.	Overall Score
Kank	App ID	* *		Amount		Score
	DD1 (0157	The University of Texas	Cancer Intervention and Prevention	Ф2 002 250	RTA-	1.0
1	RP160157	Southwestern Medical Center	Discoveries Program	\$3,993,250	Renewal	1.2
			Decoding Cellular Heterogeneity of			
2	RP160192	Baylor College of Medicine	Malignant Glioma	\$899,701	IIRA	1.3
			Protein Truncation Mutations in WIP1:			
3	RP160451	Baylor College of Medicine	Effects on Cancer and Hematopoiesis	\$900,000	IIRA	1.5
			Development of Therapeutics			
			Targeting Truncated Adenomatous			
			Polyposis Coli (APC) as a Novel			
		The University of Texas	Prevention and Intervention Strategy			
4	RP160180	Southwestern Medical Center	for Colorectal Cancer	\$900,000	IIRA	1.8
			A novel epigenetic reader as			
		The University of Texas M. D.	therapeutic target in MLL-translocated		IIRACC	
5*	RP160237	Anderson Cancer Center	pediatric leukemias	\$900,000	A	1.8
			Baylor College of Medicine			
			Comprehensive Cancer Training		RTA-	
6	RP160283	Baylor College of Medicine	Program	\$3,986,268	Renewal	1.9
		The University of Texas				
_		Health Science Center at San			IIRACC	
7	RP160487	Antonio	Cytokine signaling in Ewing sarcoma	\$1,200,000	A	1.9
			A Randomized Controlled Trial (RCT)			
			of Patient Navigation for Lung Cancer			
	DD1 60000	The University of Texas	Screening in an Urban Safety-Net	01.402 51 5	110 : 5	
8	RP160030	Southwestern Medical Center	System	\$1,492,616	IIRAP	1.9
			Promoting The Functions of Memory T			
9	RP160384	Baylor College of Medicine	cells for Adoptive T cell Therapy	\$887,676	IIRA	1.9
			Role of Long Non-Coding RNAs in			
			Breast Cancer: Identification,			
		The University of Texas	Characterization, and Determination of			
10	RP160318	Southwestern Medical Center	Molecular Functions	\$886,652	IIRA	2.0

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			Arylhydrocarbon receptor mediated			
			modulation of colorectal cancer by			
11	RP160589	Texas AgriLife Research	microbiota metabolites	\$890,840	IIRAP	2.0
- 11	Kt 100507	Texas rigitalite Research	Pediatric Radiation Oncology with	\$670,040	IIIQ II	2.0
		The University of Texas	Movie Induced Sedation Effect		IIRACC	
12**	RP160190	Southwestern Medical Center	(PROMISE)	\$900,000	A	2.0
12	100170	The University of Texas M. D.	Amplified gold nanoparticle-mediated	Ψ>00,000	7.1	2.0
13	RP160497	Anderson Cancer Center	radiosensitization of tumors	\$899,309	IIRA	2.0
13	KI 100497	Anderson Cancer Center	Imaging-based quantitative analysis of	\$699,509	ШХА	2.0
			vascular perfusion and tissue			
		The University of Texas M. D.	oxygenation to improve therapy of			
14	RP160229	Anderson Cancer Center	hepatocellular carcinoma	\$885,901	IIRA	2.0
11	10022	7 maerson cancer center	Molecular Mechanism of NLRP12-	φοσο,,, στ	11101	2.0
		The University of Texas	mediated Regulation of Colorectal			
15	RP160169	Southwestern Medical Center	Cancer	\$897,707	IIRA	2.1
		The University of Texas	DIS3L2 in Childhood Wilms Tumor:	, , , , , ,	IIRACC	
16***	RP160249	Southwestern Medical Center	Mechanism to Medicines	\$1,200,000	A	2.1
10	100249	Southwestern Medical Center	Carbamoyl Phosphate Synthase-1: A	ψ1,200,000	F 1	۷.1
		The University of Texas	new metabolic liability in non-small			
17	RP160089	Southwestern Medical Center	cell lung cancers	\$900,000	IIRA	2.1
17	100000	The Methodist Hospital	De-Orphanizing TLX: Implications for	Ψ>00,000	11101	2.1
18	RP160501	Research Institute	Glioblastomas	\$878,969	IIRA	2.1
10	KI 100301		Gilobiastomas	\$676,909	IIIA	2.1
10	DD1 (0 (22	The University of Texas		#20 2 770	HD 4 GD	2.1
19	RP160622	Southwestern Medical Center	Computational live cell histology	\$392,779	IIRACB	2.1
			Cancer Prevention Post-Graduate			
20	RP160097	Davier Callege of Medicine	Training Program in Integrative	\$2.096.900	RTA	2.1
20	KF 100097	Baylor College of Medicine The University of Texas	Epidemiology Collaborative Training of a New Cadre	\$2,986,890	KIA	2.1
		Health Science Center at	of Innovative Cancer Prevention		RTA-	
21	RP160015	Houston	Researchers	\$4,000,000	Renewal	2.1
21	KI 100013			\$4,000,000	Renewai	2.1
22	DD160240	The University of Texas	The role of the Lats kinases in	\$000 500	IID A	2.2
22	RP160340	Southwestern Medical Center	sarcomatoid renal cell carcinoma	\$899,598	IIRA	2.2
			Exploiting molecular and metabolic			
		The University of Texas M. D.	dependencies to optimize personalized			
23	RP160183	Anderson Cancer Center	therapeutic approaches for melanomas	\$900,000	IIRA	2.2
			Understanding Biological and Physical			
		m	Factors Affecting Response to Proton			
2.4	DD1 (0222	The University of Texas M. D.	Therapy to Improve its Clinical	4070 272	IID 4	2.2
24	RP160232	Anderson Cancer Center	Effectiveness	\$879,362	IIRA	2.2
			Role of Cohesin in Hematopoiesis and		IID A CC	
25	DD160022	Dealer Callege - CM- Hair	Myeloid Leukemia in Children with	¢1.005.639	IIRACC	2.2
25	RP160022	Baylor College of Medicine	Down Syndrome	\$1,905,638	A	2.2
		The University of Texas M. D.	Mechanisms and targeting strategies for			
26	RP160242	Anderson Cancer Center	SWI/SNF mutations in cancer	\$900,000	IIRA	2.3
			Targeting the undruggable: a first-in-			
	DD160446	The University of Texas	class inhibitor of the HIF-2	# 000 115	TIP :	2.2
27	RP160440	Southwestern Medical Center	transcription factor	\$899,412	IIRA	2.3

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28	RP160145	The University of Texas M. D. Anderson Cancer Center	Early Detection of Ovarian Cancer with Tumor Associated Proteins and Autoantibodies	\$1,497,595	IIRAP	2.3
29	RP160013	The University of Texas M. D. Anderson Cancer Center	Visualizing T-cell trafficking	\$900,000	IIRA	2.3
30	RP160019	The University of Texas M. D. Anderson Cancer Center	An Adaptive Personalized Clinical Trial using a Patient-Derived Xenograft Strategy to Overcome Ibrutinib Resistance in Mantle Cell Lymphoma	\$841,606	IIRA	2.3
31	RP160051	Texas A&M University System Health Science Center	Improving contrast for antibody-based tumor detection using PET	\$887,134	IIRA	2.3
32	RP160023	The University of Texas M. D. Anderson Cancer Center	Investigating the genetic and molecular mechanisms underlying RAS/ERK substrate network Novel tumorigenic mechanisms of the	\$900,000	IIRA	2.4
33	RP160211	The University of Texas Southwestern Medical Center	LKB1 tumor suppressor in endometrial and cervical cancer	\$896,653	IIRA	2.4
34	RP160319	The University of Texas Southwestern Medical Center	Role of PARP-1 in Estrogen Receptor Enhancer Function and Gene Regulation Outcomes in Breast Cancers	\$884,315	IIRA	2.4
35	RP160124	The University of Texas Health Science Center at San Antonio	Chemoprevention of Colon Cancer by Anti-inflammatory Blockade Using Neem	\$899,617	IIRAP	2.4
36	RP160188	The University of Texas M. D. Anderson Cancer Center	Regulation of infiltration and function of tumor-resident CD8 T cells by IL-15	\$828,060	IIRA	2.4
37	RP160255	The University of Texas Southwestern Medical Center	Structural and Functional Analyses of the Spindle Checkpoint	\$900,000	IIRA	2.5
38	RP160307	The University of Texas Southwestern Medical Center	Targeting Metastatic Pathways	\$900,000	IIRA	2.5
39	RP160517	The University of Texas M. D. Anderson Cancer Center	Exosomal DNA as a surrogate biomarker for early diagnosis and therapeutic stratification in pancreatic cancer	\$891,938	IIRA	2.5
40	RP160345	Baylor College of Medicine	Engineering T cells to ensure specificity for tumor cells and their environment	\$900,000	IIRA	2.5
41	RP160482	The University of Texas M. D. Anderson Cancer Center	Nanoparticle Targeted STAT3 Immune Expression Clinical Safety and Efficacy of Third	\$888,429	IIRA	2.6
42	RP160121	The University of Texas M. D. Anderson Cancer Center	party, fucosylated, cord blood derived regulatory T cells to prevent graft versus host disease	\$900,000	IIRA	2.6
43	RP160520	The University of Texas Southwestern Medical Center	Effect of Chest Radiation Therapy on Cardiomyocyte Turnover	\$897,570	IIRAP	2.6
44	RP160268	The University of Texas Southwestern Medical Center	DNA damage-induced small non- coding RNAs: mechanism and their role in cancer development	\$900,000	IIRA	2.7

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	ı	Г	T			
			Integrin-mediated IL-18 signaling in			
		The University of Texas	the prevention and treatment of			
		Health Science Center at San	inflammation-associated colorectal			
45	RP160512	Antonio	cancer	\$859,620	IIRA	2.7
			A novel function of Itch in controlling			
			IL-17-induced inflammation in colon			
46	RP160577	Baylor Research Institute	cancer	\$900,000	IIRA	2.7
			Optimizing therapeutic strategies			
		The University of Texas at	against lung cancer using Multi-			
47	RP160617	Dallas	Modality Imaging	\$899,999	IIRA	2.7
			Characterization and pharmacological			
		The University of Texas	targeting of the oncogenic activity of			
48	RP160493	Southwestern Medical Center	Jumonji enzymes	\$899,997	IIRA	2.8
			The CTC Circulator Phenotype:	Í		
			Insights into Mechanisms of Breast			
49	RP160054	Baylor College of Medicine	Cancer Dormancy	\$884,332	IIRA	2.9
49	KF 100034	The University of Texas	Regulation of tumor aggressiveness and	\$664,332	IINA	2.9
		Health Science Center at	immune suppression in lung			
50	DD160225		adenocarcinoma	000 000	IID A	2.0
50	RP160235	Houston	ı	\$900,000	IIRA	2.9
			Radiogenomic Screen to Identify Novel			
			Proliferation-associated Glioblastoma			
			Genomic Therapeutic Targets:			
5.1	DD1 601 50	The University of Texas M. D.	Discovery and Mechanistic Validation	#00 7.637	IID 4	2.0
51	RP160150	Anderson Cancer Center	Study	\$897,627	IIRA	3.0
			High resolution imaging for early and			
52	RP160460	Rice University	better detection of bladder cancer	\$873,765	IIRAP	3.0
		The University of Texas M. D.	Identifying new epigenetic	·		
53	RP160471	Anderson Cancer Center	vulnerabilities in pancreatic cancer	\$900,000	IIRA	3.1
- 55	10 100 1/1	- Indiana Canton Conton	Systematic identification of small	Ψ>00,000	11141	5.1
			molecule inhibitors that manipulate			
54	RP160462	Baylor College of Medicine	telomerase activities	\$898,288	IIRA	3.2
J-T	100402	Buylor Conege of Wicdichie	The role of Prdm16 and histone H3	\$676,266	шил	J.L
			lysine 9 methyltransferase complex in			
55	RP160035	Baylor College of Medicine	MDS	\$872,157	IIRA	3.2
33	KI 100033	Daylor College of Medicille	MIDS	\$6/4,13/	ШЛА	3.4

^{*}RP160237 - The peer review panel recommended reducing the budget to \$300,000 per year for 3 years for a total of \$900,000 based on the scope and depth of the work proposed.

^{**}RP160190 - The peer review panel recommended not funding Aim 4 (Pilot prospective clinical trial) and reducing the budget to \$300,000 per year for 3 years for a total of \$900,000. The final score was based on revised scope with full deletion of Aim 4.

^{***}RP160249 - The peer review panel recommended that given the absence of a clinical trial, the budget should be reduced to \$300,000 per year for 4 years for a total of \$1,200,000.





San Diego

Success Rate by Panel					
Peer Review	Success	Score			
Panel	Rate	Cutoff			
BCR1	10%	2.3			
BCR2	11%	3.2			
СВ	9%	3.2			
CPR	9%	2.4			
CTCR/TCR	13%	2.7			
ITI	11%	3.0			

Success Rate by Mechanism vs. Total Reviewed					
Mechanism	Success Rate	# Recommended			
IIRA	11%	39/347			
IIRACB	2%	1/50			
IIRACCA	11%	5/44			
IIRAP	13%	6/44			
RTA	14%	1/7			
RTA-R	50%	3/6			
Overall	11%	55/498			

Percent of Applications Recommended by					
Mechanism vs. Total Recommended					
Mechanism	# Recommended	Percentage			
IIRA	39/55	71%			
IIRACB	1/55	2%			
IIRACCA	5/55	9%			
IIRAP	6/55	11%			
RTA	1/55	2%			
RTA-R	3/55	5%			
Overall	55/55	100%			



CEO Affidavit Supporting Information

FY 2016—Cycle 1
Cancer Prevention Promotion and
Navigation to Clinical Services

Request for Applications



REQUEST FOR APPLICATIONS RFA P-16-PN-1

Cancer Prevention Promotion and Navigation to Clinical Services

Please also refer to the "Instructions for Applicants" document, which will be posted April 30, 2015

Application Receipt Opening Date: April 30, 2015

Application Receipt Closing Date: July 9, 2015

FY 2016

Fiscal Year Award Period

September 1, 2015-August 31, 2016

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	4.3.9. CPRIT Grants Summary (download template)	
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RFA VERSION HISTORY

Rev 4/16/15 RFA release

1. ABOUT CPRIT

The state of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the state of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Prevention Program Priorities

Legislation from the 83rd Texas Legislature requires that CPRIT's Oversight Committee establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The Prevention Program's principles and priorities will also guide CPRIT staff and the Prevention Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

Established Principles:

- Fund evidence-based interventions and their dissemination
- Support the prevention continuum of primary, secondary and tertiary (includes survivorship) prevention interventions

Prevention Program Priorities

- Prioritize populations and areas of greatest need, greatest potential for impact
- Focus on underserved populations
- Increase targeting of preventive efforts to areas where significant disparities in cancer incidence or mortality in the state exist

2. FUNDING OPPORTUNITY DESCRIPTION

2.1. Summary

The ultimate goals of the CPRIT Prevention Program are to reduce overall cancer incidence and mortality and to improve the lives of individuals who have survived or are living with cancer. The ability to reduce cancer death rates depends in part on the application of currently available evidence-based technologies and strategies. CPRIT will foster the primary, secondary, and tertiary prevention of cancer in Texas by providing financial support for a wide variety of evidence-based risk reduction, early detection, and survivorship interventions.

This Cancer Prevention Promotion and Navigation to Clinical Services (PN) RFA solicits applications for health promotion that focus on education and outreach for prevention, early detection, and survivorship of cancer for the public. In addition, this RFA requires that projects assist participants in taking action by navigating them to 1 or more prevention services being promoted. The target audiences are the general population/priority populations as defined in this RFA. CPRIT's prevention grants are intended to fund prevention interventions that have a demonstrated evidence base and are culturally appropriate for the priority population. Education and awareness are key to changing personal behaviors that lead to cancer prevention, risk reduction, and early detection, but they must be followed by strategies that motivate, initiate, and sustain behavior change. Addressing and positively influencing local policy or system change can also lead to sustainable change in desired health behaviors.

2.2. Project Objectives

CPRIT seeks to fund projects that will do the following:

- Increase the number of persons who improve their health behaviors related to the
 prevention of cancer, obtain recommended cancer screening tests or other preventive
 services, have cancers detected at earlier stages, and improve their quality of life if they
 are survivors of cancer
- Reach and serve as many people as possible and assist them in obtaining access to preventive services.
- Seek to improve processes and systems for outreach, delivery of education, and timely referral to preventive services, including improving the cost-effectiveness of those systems.

Encourage traditional and nontraditional partnerships as well as leverage existing
resources and dollars from other sources to address important knowledge gaps, increase
access to services, and achieve desired behavior changes related to cancer prevention and
control.

CPRIT expects measurable outcomes of supported activities, such as a significant and sustained change in public health behaviors (e.g., getting vaccinated, quitting smoking, getting screened) and qualitative analysis of change/improvement to systems. Applicants must demonstrate how these outcomes will ultimately impact cancer incidence, mortality, morbidity, or quality of life.

2.3. Award Description

The Cancer Prevention Promotion and Navigation to Clinical Services RFA solicits applications for projects up to 36 months in duration that will deliver public education and outreach and navigation to cancer screening and preventive services in 1 or more of the following cancer prevention and control areas:

- Primary prevention (e.g., delivery of vaccines that reduce the risk of cancer, evidencebased assessment and counseling services for behaviors established as increasing cancer risk.)
- Secondary prevention (e.g., risk-appropriate cancer screening guidelines for mammography, colonoscopy, Pap test)
- Tertiary prevention (e.g., prevention and detection of new and recurrent cancer as well as
 interventions for the consequences of cancer and its treatment, such as physical
 rehabilitation/therapy, psychosocial interventions, survivor care plans, and palliative care
 services)

Priority will be given to applications that propose innovation in the delivery of evidence- and needs-based education and outreach efforts that have the potential to create demonstrable and sustainable change in behaviors that can prevent cancer or reduce the risk of cancer within a relatively short time, leverage existing resources, navigate participants to 1 or more of the preventive services being promoted, and can demonstrate the impact on public health behaviors by individuals taking preventive measures. CPRIT strongly encourages projects to include broadbased education on cancer risk reduction and health lifestyle as one component of the education curriculum.

It is anticipated that the development time for the proposed evidence-based program(s) would be minimal and that delivery of educational program(s) to public audiences would begin no later than 6 to 8 months after the contract effective date. In addition, sufficient time should be allowed for followup after completion of the educational program(s) and navigation to services to identify behavioral changes and participant outcomes.

The applicant should demonstrate knowledge of evidence-based education, outreach, and support strategies that include navigation to clinical services; however, CPRIT is seeking projects and partnerships that will apply evidence-based strategies in novel ways that support personal behavior change, thereby leading to cancer prevention, risk reduction, and early detection and to improvements in the quality of life for survivors.

Applicants should propose active, rather than passive, education and outreach strategies that are designed to reach, engage, and motivate people and that include plans for realistic action and sustainable behavior change. Applicants must assist participants in obtaining the prevention interventions being promoted by providing navigation services (assisting with scheduling screening, etc.) and have a process for tracking participants to report on actions taken. For example, a breast cancer education project should include navigation to age- and risk-appropriate screening, followup with participants and/or professionals to confirm screening took place, and capture of the results of the screening test.

Under this RFA, CPRIT will **not** consider the following:

- Professional Education and Training programs. In this cycle, stand-alone professional
 education programs will not be considered. The proposed project must include a public
 education and navigation component. However, professional education and training to
 accomplish the goals of sustained behavior change may be proposed as one component of
 the project.
- Projects focused solely on public education. Navigation to the clinical services being
 promoted and the subsequent followup after completion of navigation to services is a
 necessary component of this mechanism and must be fully addressed.
- Projects focusing solely on case management/patient navigation services. Case
 management/patient navigation services must be paired with health promotion, education
 and outreach for prevention, early detection, and survivorship of cancer for the public.
 Furthermore, while navigation to the point of treatment of cancer is required when cancer

- is discovered through a CPRIT-funded project, applications seeking funds to provide coordination of care while an individual is in treatment are not allowed under this RFA.
- Payment for the delivery of clinical preventive services (e.g., cost of vaccines or screenings) to the public. However, applicants must assist participants in securing access to any preventive services that are being promoted. Applicants interested in including payment for the delivery of evidence-based services should submit applications under the Evidence-Based Cancer Prevention Services RFA.
- Treatment of cancer. While education on treatment options and access to treatment are
 important in reducing mortality from cancer, this award mechanism will not address
 treatment of cancer. However, applicants must ensure that public education and
 outreach programs provide information on available resources that address treatment.
- Prevention research. Research will not be funded through this award mechanism.
 Applicants interested in research should review CPRIT's Research RFAs (available at http://www.cprit.state.tx.us).

2.3.1. Priorities

Types of Cancer: CPRIT will support projects for cancers for which proven primary prevention, early detection, and tertiary prevention strategies exist. See <u>Section 2.3.2</u> for specific areas of emphasis.

Priority Populations: Priority populations are subgroups that are disproportionately affected by cancer. CPRIT-funded public education and outreach efforts must address 1 or more of these priority populations.

Priority populations include, but are not limited to, the following:

- Underinsured and uninsured individuals
- Geographically or culturally isolated populations
- Medically unserved or underserved populations
- Populations with low health literacy skills
- Geographic regions of the state with higher prevalence of cancer risk factors (e.g., obesity, tobacco use, alcohol misuse, unhealthy eating, and sedentary lifestyle)
- Racial, ethnic, and cultural minority populations

- Other populations with low screening rates, high incidence rates, and high mortality rates, focusing on individuals who are significantly out of compliance with nationally recommended screening guidelines:
 - o Individuals never before screened for colorectal cancer
 - Women never before screened for cervical cancer or who have not been screened in the past 5 years
 - Women never before screened for breast cancer or who have not been screened in the past 5 years

Geographic and Population Priority: For applications submitted in response to this announcement, at the programmatic level of review conducted by the Prevention Review Council (see Section 5.1), priority will be given to projects that target geographic regions of the state and population subgroups that are not adequately covered by the current CPRIT Prevention project portfolio (see http://www.cprit.state.tx.us/funded-grants/).

2.3.2. Specific Areas of Emphasis

Applications addressing any type of education and outreach programs that include navigation to services and that are responsive to this RFA will be considered. However, CPRIT has identified the following areas of emphasis for this cycle of awards.

CPRIT is interested in applications focused on the following:

A. Primary Prevention

Priority will be given to projects that, through evidence-based efforts, address and can positively influence local policy or systems change that can lead to sustainable change in desired health behaviors.

Tobacco Prevention and Control

- Decreasing tobacco use in areas of the state that have higher smoking rates per capita than other areas of the state.
 - Health Service Regions (HSRs) 2, 4, and 5 have significantly higher tobacco use among adults than in other regions of the state. For more information about maps of Health Service Regions, please visit

http://www.dshs.state.tx.us/regions/state.shtm

HPV Vaccination

- Increasing access to, delivery of, and completion of the HPV vaccine regimen to males and females through evidence-based intervention efforts.
 - o HPV vaccine completion rates are low (15% for males and 39% for females) across the state compared to the CDC goals of 75% completion rates.¹

Liver Cancer

- Decreasing disparities in incidence and mortality rates for hepatocellular cancer (HCC)
 by increasing the provision of vaccination and screening for hepatitis B virus and
 screening for hepatitis C virus (following US Preventive Services Task Force [USPSTF]
 guidelines), diagnostic testing, navigation that ensures access to viral treatment, and
 education on risk factors and on reducing transmission of hepatitis.
 - HCC incidence is significantly higher in Texas Hispanics, blacks, and Asian/Pacific Islanders than in non-Hispanic whites.²
 - Significantly higher HCC rates in Texas Hispanics versus the United States are driven by very high rates among Hispanics in South Texas.²
 - o Males have significantly higher incidence and mortality rates than females.²
 - Age at diagnosis is shifting toward younger patients, both in Texas and the United States. ²

B. Secondary Prevention - Screening and Early Detection Services

Applicants should select preventive services using current evidence-based national clinical guidelines (e.g., USPSTF, American Cancer Society).

Colorectal Cancer

- Increasing screening/detection rates in HSRs 1 through 6 and HSR 9.
 - The highest rates of cancer incidence mortality are found in these regions of Texas.²
- Decreasing disparities in incidence and mortality rates of colorectal cancer for racial/ethnic populations and rural communities.
 - African Americans have the highest incidence and mortality rates, followed by non-Hispanic whites and Hispanics.²

- Decreasing incidence and mortality rates in rural counties.
 - Incidence and mortality rates are higher in rural counties compared to urban counties ²

Cervical Cancer

- Increasing screening/detection rates for women in Texas-Mexico border counties.
 - Women in these counties have a 30% higher cervical cancer mortality rate than women in nonborder counties.²
- Decreasing disparities in racial/ethnic populations.
 - Hispanics have the highest incidence rates, while African Americans have the highest mortality rates.²
- Reaching women never before screened.

Breast Cancer

- Increasing screening/detection rates in rural and medically underserved areas of the state
- Reaching women never before screened

Data on cancer incidence and mortality is provided by the Texas Cancer Registry.² For more information about cancer in Texas, visit CPRIT's website at

http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control or visit the Texas Cancer Registry site at http://www.dshs.state.tx.us/tcr/

C. Tertiary Prevention - Survivorship Services

Priority for funding will be given to survivorship projects that demonstrate a likelihood of success based on available evidence and that can demonstrate and measure an improvement in quality of life in 1 of more of the following areas:

- Preventing secondary cancers and recurrence of cancer
- Managing the aftereffects of cancer and treatment to maximize quality of life and number of years of healthy life
- Minimizing preventable pain, disability, and psychosocial distress

Applicants proposing survivorship projects may address people with any type of cancer.

2.3.3. Outcome Metrics

The applicant is required to describe final outcome measures for the project. Applicants must evaluate changes in participants' knowledge and behavior/performance after the program. Applicants are required to clearly describe their assessment and evaluation methodology and to provide baseline data describing how funds from the CPRIT grant will improve outcomes over baseline. In the case where no baseline data exist for the priority population, the applicant must present clear plans and describe method(s) of measurement used to collect the data necessary to establish a baseline at the beginning of the proposed project. Similarly, applicants with previously or currently funded CPRIT projects are required to provide a summary of the project results and how the current application builds on the previous work or addresses new areas of cancer prevention and control services. All projects are required to follow up and identify the effectiveness of the proposed intervention (e.g., impact of system changes, adherence to screening guidelines, number of participants who took action and received primary prevention or screening services).

Reporting Requirements

Funded projects are required to report quantitative output and outcome metrics (as appropriate for each project) through the submission of quarterly progress reports, annual reports, and a final report.

Quarterly progress report sections include, but are not limited to, the following:

- Narrative on project progress (required)
- People reached activities
- Services, other than clinical services, provided to the public/professionals
- Actions taken by people/professionals as a result of education or training, including number of people reporting sustained behavior change
- Clinical services provided
- Abnormal results and precursors or cancers detected

Annual and Final progress report sections include, but are not limited to, the following:

 Key accomplishments, including qualitative analysis of policy change and/or lasting systems change

- Progress against goals and objectives, including percentage increase over baseline in provision of age- and risk-appropriate education and navigation services to eligible men and women in a defined service area; for example:
- Percentage increase over baseline in number of people served
- Percentage increase over baseline in number of education and navigation services provided
- Percentage increase over baseline in cancers and precancers detected, if applicable
- Percentage increase in early-stage cancer diagnoses in a defined service area, if applicable

Outcome metrics may include, but are not limited to, the following:

- The increase over baseline in the number of persons in priority populations who take
 preventive actions (e.g., change behavior, access services through navigation, receive
 counseling) as a result of participating in the educational program.
- In addition, interim measures may include the increase over baseline in the number of
 persons who were assisted in securing access to the appropriate clinical services through
 navigation and were appropriately counseled about health behaviors and evidence-based
 screening guidelines.
- Materials produced and publications
- Economic impact of the project

2.4. Eligibility

- The applicant must be a Texas-based entity, such as a community-based organization, health institution, government organization, public or private company, college or university, or academic health institution.
- The designated Program Director (PD) will be responsible for the overall performance of the funded project. The PD must have relevant education and management experience and must reside in Texas during the project performance time.
- The evaluation of the project must be headed by a professional who has demonstrated expertise in the field (e.g., qualitative or quantitative statistics) and who resides in Texas during the time that the project is conducted.

- The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PD, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant may submit more than 1 application, but each application must be for
 distinctly different services without overlap in the services provided. Applicants who do
 not meet this criterion will have all applications administratively withdrawn without peer
 review.
- If the applicant or a partner is an existing DSHS contractor, CPRIT funds may not be
 used as a match, and the application must explain how this grant complements or
 leverages existing state and federal funds. DSHS contractors who also receive CPRIT
 funds must be in compliance with and fulfill all contractual obligations within CPRIT.
 CPRIT and DSHS reserve the right to discuss the contractual standing of any contractor
 receiving funds from both entities.
- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the state of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant organization is eligible to receive a grant award only if the applicant
 certifies that the applicant organization, including the PD, any senior member or key
 personnel listed on the grant application, or any officer or director of the grant applicant's
 organization (or any person related to 1 or more of these individuals within the second
 degree of consanguinity or affinity), has not made and will not make a contribution to
 CPRIT or to any foundation created to benefit CPRIT.
- The applicant must report whether the applicant organization, the PD, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, (whether slated to receive salary or compensation under the grant award or not), are currently ineligible to receive federal grant funds because of scientific misconduct or

- fraud or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. CPRIT grants are funded on a reimbursement-only basis. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in Section 6. All statutory provisions and relevant administrative rules can be found at http://www.cprit.state.tx.us.

2.4.1. Resubmission Policy

More than **1 resubmission** is not permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PD for a project or a change of title for a project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission

2.5. Funding Information

Applicants may request any amount of funding up to a maximum of \$400,000 in total funding over a maximum of 36 months. Budget requests for funding will vary depending on the project, and it is anticipated that the majority of projects will request significantly less than the maximum.

Grant funds may be used to pay for salary and benefits, project supplies, equipment, costs for outreach and education of populations, and travel of project personnel to project site(s). Equipment requests (\$5,000 and above) will receive a case-by-case evaluation and be carefully scrutinized. Requests for funds to support construction, renovation, or any other infrastructure needs are not appropriate for this mechanism, nor are requests to support lobbying or to attend out-of-state professional meetings. Grantees may request funds for travel for 2 project staff to attend CPRIT's conference.

The budget should be proportional to the number of individuals receiving programs and services, and a significant proportion of funds is expected to be used for program and service delivery as

opposed to program development. In addition, CPRIT seeks to fill gaps in funding rather than replace existing funding, supplant funds that would normally be expended by the applicant's organization, or make up for funding reductions from other sources. CPRIT does not provide support for projects when funds are readily available from other sources. Furthermore, CPRIT funds may not be used for any costs under this award that should be billed to any other funding source.

3. KEY DATES

RFA

RFA release April 16, 2015

Application

Online application opens April 30, 2015, 7 AM central time

Application due July 9, 2015, 3 PM central time

Application review September 2015

Award

Award notification November 2015

Anticipated start date December 2015

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

4. APPLICATION SUBMISSION GUIDELINES

4.1. Instructions for Applicants document

It is imperative that applicants read the accompanying instructions document for this RFA (https://CPRITGrants.org). Requirements may have changed from previous versions.

4.2. Online Application Receipt System

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted at this portal will be considered eligible for review. The PD must create a user account in the system to start and submit an application. The Co-PD, if applicable, must also create a user account to participate in the

application. Furthermore, the Application Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on April 30, 2015, and must be submitted by 3 PM central time on July 9, 2015. Detailed instructions for submitting an application are in the *Instructions for Applicants* document, posted on CARS.

Submission of an application is considered an acceptance of the terms and conditions of the RFA.

4.2.1. Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via email to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

4.3. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Refer to the *Instructions for Applicants* document for details.

Submissions that are missing 1 or more components or do not meet the eligibility requirements will be administratively withdrawn without review.

4.3.1. Abstract and Significance (5,000 characters)

Clearly explain the problem(s) to be addressed, the approach(es) to the solution, and how the application is responsive to this RFA. In the event that the project is funded, the abstract will be made public; therefore, no proprietary information should be included in this statement. Initial compliance decisions are based in part upon review of this statement.

The required abstract format is as follows (use headings as outlined below):

- Need: Include a description of need in the specific service area. Include rates of
 incidence, mortality, and screening in the service area compared to overall Texas rates.
 Describe barriers, plans to overcome these barriers, and the priority population to be
 served.
- Overall Project Strategy: Describe the project and how it will address the identified need. Clearly explain what the project is and what it will specifically do, including the

- education, outreach, and navigation services to be provided, and the process/system for delivery of education, outreach, and navigation services to the priority population.
- **Specific Goals:** State specifically the overall goals of the proposed project; include the estimated overall numbers of people (public and/or professionals) reached and people (public and/or professionals) served.
- **Innovation:** Describe the creative components of the proposed project and how it differs from current programs or education, outreach, and navigation services being provided.
- **Significance and Impact:** Explain how the proposed project, if successful, will have a unique and major impact on cancer prevention and control for the population proposed to be served and for the state of Texas.

4.3.2. Goals and Objectives

List specific goals and **measurable** objectives for each year of the project. A baseline and method(s) of measurement are required for each objective. Provide both raw numbers and percent changes for the baseline and target. Applicants must explain plans to establish baseline and describe method(s) of measurement in cases where a baseline has not been defined.

4.3.3. Project Timeline

Provide a project timeline for project activities that includes deliverables and dates. Use Years 1, 2, 3 and months 1,2,3, etc., as applicable instead of specific months or years (e.g., Year 1, Months 3-5, not 2017, March – May).

4.3.4. Project Plan (15 pages maximum; fewer pages permissible)

The required project plan format follows. Applicants must use the headings outlined below. Applications not following the required format will be administratively withdrawn.

Background: Briefly present the rationale for the proposed project, emphasizing the pressing problem in cancer prevention that will be addressed and how the project will have a major impact on changing peoples' behaviors to prevent cancer, reduce the risk of cancer, or improve the quality of life for survivors within a relatively short time frame. Describe creative components of the proposed project. Clearly demonstrate the ability to complete the proposed project and describe how results will be improved over baseline knowledge and personal

behaviors. Clearly demonstrate the ability to reach the priority population. Describe the geographic region of the state that the project will serve; maps are appreciated.

Goals and Objectives (optional): Goals and Objectives will be entered in separate fields in CARS and need not be provided in the project plan. However, if desired, goals and objectives may be fully repeated or briefly summarized here.

Components of the Project: Clearly describe the need, education and outreach design and delivery methods, navigation to preventive services, and evidence base (provide references) for the project as well as instructors and anticipated results. Be explicit about the base of evidence and any necessary adaptations for the proposed project. Describe why this project is nonduplicative, creative, or unique. Clearly demonstrate the ability to provide the proposed education, outreach, and navigation services, and describe how results will be improved over baseline and the ability to reach the priority population. Applicants must also clearly describe plans to ensure access to treatment services should cancer be detected.

Evaluation Strategy: A strong commitment to evaluation of the project is required. Describe the impact on ultimate outcome measures and interim outcome measures as outlined in Section 2.3.3. Describe the plan for outcome measurements, including data collection and management methods, statistical analyses, and anticipated results. Evaluation and reporting of outcomes must be headed by a professional who has demonstrated expertise in the field of program evaluation, intervention science, cancer screening, and/or behavioral risk reduction. If needed, applicants may want to consider seeking expertise at Texas-based academic cancer centers, schools/programs of public health, prevention research centers, or the like. Applicants should budget accordingly for the evaluation activity and should involve that professional during grant application preparation to ensure, among other things, that the evaluation plan is linked to the proposed goals and objectives.

Organizational Qualifications and Capabilities: Describe the organization and its track record and success in providing programs and services. Describe the role and qualifications of the key collaborators/partners in the project. Include information on the organization's financial stability and viability. To ensure access to preventive services and reporting of services outcomes, applicants should demonstrate that they have provider partnerships and agreements (via memoranda of understanding) or commitments (via letters of commitment) in place.

Integration and Capacity Building: CPRIT funds projects that target the unmet needs not sufficiently covered by other funding sources, and full maintenance of the project may not be feasible. This is especially the case when the project involves the delivery of clinical services. Educational and other less costly interventions may be more readily sustained. Full maintenance of a project, the ability of the grantee's setting or community to continue to deliver the health benefits of the intervention as funded, is not required; however, efforts toward maintenance should be described.

It is expected that steps toward integration and capacity building for components of the project will be taken and plans for such be fully described in the application. *Integration* is defined as the extent the evidence-based intervention is integrated within the culture of the grantee's setting or community through policies and practice. *Capacity building* is any activity (e.g., training, identification of alternative resources, building internal assets) that builds durable resources and enables the grantee's setting or community to continue the delivery of <u>some or all</u> components of the evidence-based intervention.

Elements of integration and capacity building may include, but are not limited to, the following:

- Developing ownership, administrative networks, and formal engagements with stakeholders
- Developing processes for each practice/location to incorporate services into its structure beyond project funding
- Identifying and training of diverse resources (human, financial, material, and technological)
- Implementing policies to improve effectiveness and efficiency (including costeffectiveness) of systems

Dissemination and Scalability (Expansion): Describe how the project lends itself to dissemination to or application by other communities and/or organizations in the state or expansion in the same communities. Describe plans for dissemination of positive and negative project results and outcomes. Dissemination of project results and outcomes, including barriers encountered and successes achieved, is critical to building the evidence base for cancer prevention and control efforts in the state. Dissemination methods may include, but are not limited to, presentations, publications, abstract submissions, and professional journal articles, etc.

4.3.5. People Reached (complete online)

Provide the estimated overall number of people (members of the public and professionals) to be reached by the funded project. The applicant is required to itemize separately the noninteractive education and outreach activities, with estimates, that led to the calculation of the overall estimates provided. Refer to the <u>Appendix</u> for definitions.

4.3.6. People Served (complete online)

Provide the estimated overall number of people (members of the public and professionals) to be served by the funded project. The applicant is required to itemize separately the education, navigation, and clinical activities/services, with estimates, that led to the calculation of the overall estimates provided. Refer to the Appendix for definitions.

4.3.7. References

Provide a concise and relevant list of references cited for the application. The successful applicant will provide referenced evidence of need and literature support for the proposed education and outreach methods.

4.3.8. Resubmission Summary (if applicable; download template)

Describe the approach to the resubmission and how reviewers' comments were addressed. The summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission; the applicant is not responsible for providing this document.

4.3.9. CPRIT Grants Summary (download template)

Provide a description of the progress or final results of **all** CPRIT-funded projects of the PD or Co-PD, regardless of their connection to this application. Indicate how the current application builds on the previous work or addresses new areas of cancer prevention and control services. Applications that are missing this document and for which CPRIT records show a PD and/or Co-PD with previous or current CPRIT funds will be administratively withdrawn.

4.3.10. Budget and Justification (complete online)

Provide a brief outline and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, travel, equipment, supplies, contractual expenses, services delivery, and other expenses. CPRIT funds will be distributed on a reimbursement basis.

Applications requesting more than the maximum allowed cost (total costs) as specified in Section 2.5 will be administratively withdrawn.

- Cost Per Person Served: The cost per person served will be automatically calculated from the total cost of the project divided by the total number of people (both public and professionals) served (refer to Appendix). A significant proportion of funds is expected to be used for program delivery as opposed to program development and organizational infrastructure.
- **Personnel:** The individual salary cap for CPRIT awards is \$200,000 per year. Describe the source of funding for all project personnel where CPRIT funds are not requested.
- **Travel:** PDs and related project staff are expected to attend CPRIT's conference. CPRIT funds may be used to send up to 2 people to the conference.
- Equipment: Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application. Justification must be provided for why funding for this equipment cannot be found elsewhere; CPRIT funding should not supplant existing funds. Cost sharing of equipment purchases is strongly encouraged.
- Services Costs: CPRIT reimburses for services using Medicare reimbursement rates.
 Describe the source of funding for all services where CPRIT funds are not requested.

• Other Expenses

- o **Incentives:** Use of incentives or positive rewards to change or elicit behavior is allowed; however, incentives may only be used based on strong evidence of their effectiveness for the purpose and in the priority population identified by the applicant. CPRIT will not fund cash incentives. The maximum dollar value allowed for an incentive per person, per activity or session, is \$25.
- Indirect Costs: It is CPRIT's policy not to allow recovery of indirect costs for prevention programs.
- Costs Not Related to Cancer Prevention and Control: CPRIT does not allow recovery of any costs for services not related to cancer (e.g., health physicals, HIV testing).

4.3.11. Current and Pending Support and Sources of Funding (download template)

Describe the funding source and duration of all current and pending support for the proposed project, including a capitalization table that reflects private investors, if any. Information for the initial funded project need not be included.

4.3.12. Biographical Sketches (download template)

The designated PD will be responsible for the overall performance of the funded project and must have relevant education and management experience. The PD/Co-PD(s) must provide a biographical sketch that describes his or her education and training, professional experience, awards and honors, and publications and/or involvement in programs relevant to cancer prevention and/or service delivery.

The evaluation professional must provide a biographical sketch.

Up to 3 additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed 2 pages.

Only biographical sketches will be accepted; do not submit resumes and CVs.

4.3.13. Collaborating Organizations (complete online)

List all key participating organizations that will partner with the applicant organization to provide 1 or more components essential to the success of the program (e.g., evaluation, clinical services, recruitment to screening).

4.3.14. Letters of Commitment

Applicants should provide letters of commitment and/or memoranda of understanding from community organizations, key faculty, or any other component essential to the success of the program.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively withdrawn without review.

5. APPLICATION REVIEW

5.1. Review Process Overview

All eligible applications will be reviewed using a 2-stage peer review process: (1) evaluation of applications by peer review panels and (2) prioritization of grant applications by the Prevention Review Council. In the first stage, applications will be evaluated by an independent review panel using the criteria listed below. In the second stage, applications judged to be meritorious by review panels will be evaluated by the Prevention Review Council and recommended for funding based on comparisons with applications from all of the review panels and programmatic priorities. Programmatic considerations may include, but are not limited to, geographic distribution, cancer type, population served, and type of program or service. The scores are only 1 factor considered during programmatic review. At the programmatic level of review, priority will be given to proposed projects that target geographic regions of the state or population subgroups that are not well represented in the current CPRIT Prevention project portfolio.

Applications approved by Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

Each stage of application review is conducted confidentially, and all CPRIT Peer Review Panel members, Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Peer Review Panel members and Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer Review Panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee Member, a PIC Member, a Review Panel member, or a Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention and Communications Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when preapplications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

5.2. Review Criteria

Peer review of applications will be based on primary scored criteria and secondary unscored criteria, identified below. Review panels consisting of experts in the field and advocates will evaluate and score each primary criterion and subsequently assign an overall score that reflects an overall assessment of the application. The overall evaluation score will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application and responsiveness to the RFA priorities.

5.2.1. Primary Evaluation Criteria

Impact and Innovation

• Does clear evidence exist of an important need for this public education, and can that education effectively address the need? Are the goals and priorities of the project responsive to the RFA?

- Does the proposed project demonstrate creativity, ingenuity, resourcefulness, or imagination? Does it take evidence-based interventions and apply them in innovative ways, going beyond "doing what has always been done" to explore new partnerships, new audiences, or improvements to systems?
- Does the program address known gaps in cancer prevention education and access to preventive services and avoid duplication of effort?
- If applicable, have collaborative partners demonstrated that the collaborative effort will provide a greater impact on cancer prevention and control than each individual organization's effort separately?
- Will the project reach and serve an appropriate number of people based on the budget submitted?

Project Strategy and Feasibility

- Does the proposed project provide education and outreach programs specified in the RFA?
- Does the project provide the required access or navigation to preventive services following educational activities? Are partnerships with service providers clearly and convincingly described?
- Are the overall program approach and strategy clearly described and supported by
 established theory and practice as well as evidence-based interventions? Are the base of
 evidence and any necessary adaptations clearly explained and referenced?
- Are the proposed objectives and activities feasible within the duration of the award? Has the applicant convincingly demonstrated the short- and long-term impacts of the project?
- Is the priority population as well as culturally appropriate methods to reach the priority population clearly described? Are barriers for the population clearly described, and are plans to provide culturally appropriate education to overcome these barriers clearly addressed?
- Does the program leverage partners and resources to maximize the reach of the program proposed? Does the program leverage and complement other state, federal, and nonprofit grants?

Outcomes Evaluation

- Are specific goals and measurable objectives for each year of the project provided?
- Are the proposed outcome measures appropriate for the project, and are the expected changes significant?
- Does the application provide a clear and appropriate plan for data collection and management, statistical analyses, and interpretation of results to follow, measure, and report on the project's outcomes?
- Are clear baseline data provided for the priority population, or are clear plans and methods of measurements included to collect baseline data at the beginning of the proposed project?
- If an evidence-based intervention is being adapted in a population where it has not been tried/tested, are plans for evaluation of barriers, effectiveness, and fidelity to the model described?
- Is the qualitative analysis of planned policy or system changes described?

Organizational Qualifications and Capabilities

- Do the organization and its collaborators/partners demonstrate the ability to provide the
 proposed preventive services? Does the described role of each collaborating organization
 make it clear that each organization adds value to the project and is committed to
 working together to implement the project?
- Have the appropriate personnel been recruited to implement, evaluate, and complete the project?
- Is the organization structurally and financially stable and viable?

Integration and Capacity Building

- Does the applicant describe steps that will be taken and components of the project that will be integrated into the organization through policies and practices?
- Does the applicant describe steps that will be taken or components of the project that will remain (e.g., trained personnel, identification of alternative resources, building internal assets) to continue the delivery of <u>some or all</u> components of the evidence-based intervention once CPRIT funding ends.

5.2.2. Secondary Evaluation Criteria

Secondary criteria contribute to the global score assigned to the application. Lack of information or clarity on these criteria may result in a lower global score. Included in the secondary evaluation criteria are the following:

Budget

- Is the budget appropriate and reasonable for the scope and services of the proposed work?
- Is the cost per person served appropriate and reasonable?
- Is the proportion of the funds allocated for direct services reasonable?
- Is the project a good investment of Texas public funds?

Dissemination and Scalability

Dissemination of positive and negative project results and outcomes, including barriers encountered and successes achieved, is critical to building the evidence base for cancer prevention and control efforts in the state. Dissemination methods can include, but are not limited to, presentations, publications, abstract submissions, and professional journal articles, etc.

 Are plans for dissemination of the project's results (both positive and negative) clearly described?

While scalability of programs is desirable, some programs may have unique resources and may not lend themselves to replication by others. However, some components of the project may lend themselves to modification and replication.

• Does the program lend itself to scalability/expansion by others in the state? If so, does the application describe a plan for doing so?

6. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports.

Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's administrative rules, which are available at http://www.cprit.state.tx.us. Applicants are advised to review CPRIT's administrative rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires the PD of the award to submit quarterly, annual, and final progress reports. These reports summarize the progress made toward project goals and address plans for the upcoming year and performance during the previous year(s). In addition, quarterly fiscal reporting and reporting on selected metrics will be required per the instructions to award recipients. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract.

7. CONTACT INFORMATION

7.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding the scope and focus of applications. Before contacting the HelpDesk, please refer to the *Instructions for Applicants* document (posted by April 30, 2015), which provides a step-by-step guide to using the Application Receipt System.

Dates of operation: April 30, 2015, to July 9, 2015 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time

Wednesday, 8 AM to 4 PM central time

Tel: 866-941-7146

Email: Help@CPRITGrants.org

7.2. Program Questions

Questions regarding the CPRIT Prevention Program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Prevention Program Office.

Tel: 512-305-8422

E-mail: <u>Help@CPRITGrants.org</u>

Website: www.cprit.state.tx.us

8. CONFERENCE CALLS TO ANSWER APPLICANT QUESTIONS

CPRIT will host a webinar to provide an overview of this RFA and a demonstration of CARS. A programmatic and technical question-and-answer session will be included. Applicants should sign up for CPRIT's electronic mailing list at http://www.cprit.state.tx.us to ensure that they receive notification of this webinar.

9. **RESOURCES**

- The Texas Cancer Registry: http://www.dshs.state.tx.us/tcr
- The Community Guide http://www.thecommunityguide.org/index.html
- Cancer Control P.L.A.N.E.T. http://cancercontrolplanet.cancer.gov
- Guide to Clinical Preventive Services: Recommendations of the U.S. Preventive Services
 Task Force. http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/
- Brownson, RC, Colditz GA, and Proctor, EK (Editors), Dissemination and
 Implementation Research in Health: Translating Science to Practice. Oxford University
 Press, March 2012.

- Centers for Disease Control and Prevention: The Program Sustainability Assessment
 Tool: A New Instrument for Public Health Programs
 http://www.cdc.gov/pcd/issues/2014/13_0184.htm
- Centers for Disease Control and Prevention: Using the Program Sustainability Tool to
 Assess and Plan for Sustainability http://www.cdc.gov/pcd/issues/2014/13 0185.htm
- Centers for Disease Control and Prevention. Distinguishing Public Health Research and Public Health Non research. http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf.

10. REFERENCES

- 1. http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm/
- 2. Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas

 Department of State Health Services, http://www.dshs.state.tx.us/tcr/default.shtm

11. APPENDIX: KEY TERMS

- **Activities:** A listing of the "who, what, when, where, and how" for each objective that will be accomplished.
- Capacity Building: Any activity (e.g., training, identification of alternative resources, building internal assets) that builds durable resources and enables the grantee's setting or community to continue the delivery of some or all components of the evidence-based intervention.
- Clinical Services: Number of clinical services such as screenings, diagnostic tests, vaccinations, counseling sessions, or other evidence-based preventive services delivered by a health care practitioner in an office, clinic, or health care system. Other examples include genetic testing or assessments, physical rehabilitation, tobacco cessation counseling or nicotine replacement therapy, case management, primary prevention clinical assessments, and family history screening.
- Education Services: Number of evidence-based, culturally appropriate cancer
 prevention and control education and outreach services delivered to the public and to
 health care professionals. Examples include education or training sessions (group or
 individual), focus groups, and knowledge assessments.

- Evidence-Based Program: A program that is validated by some form of documented research or applied evidence. CPRIT's website provides links to resources for evidence-based strategies, programs, and clinical recommendations for cancer prevention and control. To access this information, visit
 http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control
- Goals: Broad statements of general purpose to guide planning. Goals should be few in number and focus on aspects of highest importance to the project.
- **Integration:** The extent the evidence-based intervention is integrated within the culture of the grantee's setting or community through policies and practice.
- Navigation Services: Number of unique activities/services that offer assistance to help
 overcome health care system barriers in a timely and informative manner and facilitate
 cancer screening and diagnosis to improve health care access and outcomes. Examples
 include patient reminders, transportation assistance, and appointment scheduling
 assistance.
- **Objectives:** Specific, **measurable**, actionable, realistic, and timely projections for outputs and outcomes. Example: "Increase screening service provision in X population from Y% to Z% by 20xx." Baseline data for the priority population must be included as part of each objective.
- People Reached: Number of members of the public and/or professionals reached via noninteractive public or professional education and outreach activities, such as mass media efforts, brochure distribution, public service announcements, newsletters, and journals. This category includes individuals who would be reached through activities that are directly funded by CPRIT as well as individuals who would be reached through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project.
- People Served: Number of members of the public and/or professionals served via direct, interactive public or professional education, outreach, training, navigation service delivery, or clinical service delivery, such as live educational and/or training sessions, vaccine administration, screening, diagnostics, case management/navigation services, and physician consults. This category includes individuals who would be served through activities that are directly funded by CPRIT as well as individuals who would be served through activities that occur as a direct consequence of the CPRIT-funded project's

leveraging of other resources/funding to implement the CPRIT-funded project (e.g., X people screened for cervical cancer after referral to Y indigent care program as a result of CPRIT-funded navigation services performed by the project).

Third Party Observer Reports



CPRIT Peer Review Meeting Observation Report

Report #2015-09-21/22-PRE

Program Name: Prevention

Panel Name: FY16.1 Prevention Peer Review Panel - 1

Panel Date: September 21, 2015 to September 22, 2015

Report Date: September 30, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Peer Review Panel-1 peer review of applications for FY16 funding. The meeting was co-chaired by Ross Brownson and Nancy Lee and held at the Hyatt Regency in Dallas TX on September 21 through September 22, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Prevention Peer Review Panel-1 panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and co-chaired by Ross Brownson and Nancy Lee on September 21 through September 22, 2015.

The independent observer noted the following during our observation:

- Sixteen applications were discussed within the Prevention Peer Review Meeting Panel to determine
 which grants would receive CPRIT funding.
- Eleven peer review panelists, two advocate reviewers, four CPRIT staff members and five SRA
 employees were present on September 21, 2015. Eleven peer review panelists, two advocate reviewers,
 three CPRIT staff members and five SRA employees were present on September 22, 2015.
- Eight conflicts of interest were identified prior to or during the meeting. Applications for seven
 conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest either
 left the room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Prevention Review Council Meeting Observation Report

Report #2015-10-23-PREV

Program Name: Prevention

Panel Name: FY16.1 Prevention Review Council

Programmatic Review

Panel Date: October 23, 2015 Report Date: October 29, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Review Council Programmatic Review peer review of applications for FY16 funding. The meeting was chaired by Stephen Wyatt and held via teleconference on October 23, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Prevention Review Council Programmatic Review held via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Stephen Wyatt on October 23, 2015.

The independent observer noted the following during our observation:

- Sixteen applications were discussed within the Prevention Review Council Meeting to determine which
 grants would receive CPRIT funding.
- Three peer review panelists, two CPRIT staff members and one SRA employee were present for the meeting.
- One conflict of interest was identified prior to or during the meeting. Applications for one conflict was
 discussed during the peer review panel. The reviewer with the conflict of interest either left the room
 or did not participate telephonically and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Prevention Cycle 16.1 Applications (Prevention Cycle 16.1 Awards Announced at November 19, 2015, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Prevention Cycle 16.1 include Cancer Prevention Promotion and Navigation to Clinical Services, Competitive Continuation/Expansion—Evidence-Based Cancer Prevention Services, Evidence-Based Cancer Prevention Services, Evidence-Based Cancer Prevention Services - Colorectal Cancer Prevention Coalition, and Dissemination of CPRIT-Funded Cancer Prevention and Control Interventions. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted
Applica	tions considered by the	e PIC and Oversight Co	mmittee
PP160023	Sauter, Edward	The University of Texas Health Center at Tyler	Schwartz, Randy; Cole, Kirk
PP160027	Foxhall, Lewis	The University of Texas M.D. Anderson Cancer Center	Vanderpool, Robin; Cole, Kirk
PP160042	Parra-Medinca, Deborah	The University of Texas Health Science Center at San Antonio	Vanderpool, Robin
PP160046	Cuccaro, Paula	The University of Texas Health Science Center at Houston	Vanderpool, Robin
PP160047	Savas, Lara	The University of Texas Health Science Center at Houston	Brownson, Ross
PP160048	Bolin, Jane	Texas A&M University System Health Science Center	Escabedo, Luis; Cole, Kirk
PP160051	Fernandez, Maria	Texas A&M University System	Cole, Kirk

Application ID	Applicant	Institution	Conflict Noted							
		Health Science								
		Center								
Applications Not Recommended for PIC or Oversight Committee Consideration										
PP160026	Handal, Gilbert	Texas Tech	Escobedo, Luis							
		University Health								
		Sciences Center at El								
		Paso								
PP160043	Gonzalez, Hector	City of Laredo Health	Escobedo, Luis							
		Department								

De-Identified Overall Evaluation Scores

Cancer Prevention Promotion and Navigation to Clinical Services

Prevention Cycle 16.1

Application ID	Final Overall Evaluation Score
PP160032*	3.0
PP160056*	3.0

^{*=}Recommended for funding

Final Overall Evaluation Scores and Rank Order Scores

Pete Geren
Oversight Committee Presiding Officer
Cancer Prevention and Research Institute of Texas
Via email to pgcprit@sidrichardson.org

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Mr. Roberts and Mr. Geren,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for CPRIT Prevention grant awards. The applicants on the attached list of submitted proposals responded to CPRIT requests for applications (RFA) released for the first review cycle of FY2016. These recommendations reflect 50+ hours of work by individual reviewers and include panel discussion of the applicants' proposals, in addition to the PRC's programmatic review.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are provided for each grant application. The PRC did not make changes to the goals, timelines, or project objectives requested by the applicants. When the PRC did not follow the rank ordered scores in developing its recommended funding order a justification, based upon established programmatic priorities outlined in the RFAs, is provided.

The projected funding available for this fiscal year is \$27,965,885. However, the recent interpretation that annual prevention program funding is 10% of the CPRIT awarded dollars within a fiscal year could impact the dollars available. With the second funding cycle for the fiscal year underway, the PRC opted for a conservative approach to its recommendations for this cycle. Recommendations are provided at two levels: (1) initially fund 12 projects totaling an estimated \$13,247,742 and (2) depending upon the availability of funds later in the fiscal year, fund an additional 2 projects (PP160046 and PP160033 totaling \$2,999,657).

Our recommendations meet the PRC's standards for grant award funding of projects that are evidence-based, deliver programs or services to underserved populations, and focus on primary, secondary or tertiary prevention. In making these recommendations the PRC also considered the available funding, the composition of the current portfolio, and the programmatic priorities in the RFA which include potential for impact and return on investment, geographic distribution, cancer type and type of program. All of the recommended grants address one or more of the Prevention Program priorities.

Sincerely,

Stephen W. Wyatt, DMD, MPH Chair, CPRIT Prevention Review Council

App ID	Mech ·	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP16004 9	CCE- EBP	Expansion of a comprehensive cervical cancer screening program for medically underserved women in Harris County	Anderson, Matthew L	Baylor College of Medicine	\$1,500,000	1.9			1	
PP16004 7	CCE- EBP	A community based program to increase breast and cervical cancer screening and HPV vaccination to reduce the impact of breast and certical cancer among Latinas	Savas, Lara S	The University of Texas Health Science Center at Houston	\$1,387,005	2.7	Steps that will be taken to assess actual # of screenings and vaccinations for participants in educational sessions are not explained. It appears that only women completing the surveys will be followed. Evaluation of outcomes for all participants is not provided, only provided for women completing surveys. Budget is unclear about number of screenings that will be paid for; number of financially supported	Changes not recommended-PRC reviewed peer review comments and determined those comments did NOT impact decision to recommend or impact rank order	2	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							screening isn't clearly stated.			
PP16004 2	EBP	Using Best Practices to Promote HPV vaccination in Rural Primary Care Settings	Parra- Medina, Deborah	The University of Texas Health Science Center at San Antonio	\$1,295,493	2.8	Outcomes evaluation doesn't have baseline and % increase noted. A highly intensive program is being implemented and the high cost is a barrier. If the cost is reduced, the applicability of the proposed approach may be enhanced. Reviewers would like the applicants to clarify why the increase in the budget from the previous grant to this grant. Why has the per person	changes not recommended- PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	3	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							cost increased so much?			
PP16003 2	PN	Family Health History-based Colorectal Cancer Prevention and Navigation to Clinical Services among Uninsured Chinese Americans in Texas	Chen, Lei- Shih	Texas A&M University	\$399,993	3.0	Findings from this study should be applied to follow-up treatment for the participants. Plans for this are lacking and should be provided.	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	4	
PP16005 6	PN	REACH Rural Education and Awareness for Community Health	Hoelscher, Bill	Coastal Bend Wellness Foundatio n	\$379,698	3.0	Should be clarified that \$25 gift card is not being offered to change the behavior of the participants.	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	5	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP16001 0	EBP	Maximizing opportunities for HPV vaccination in the Golden Triangle	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	\$1,409,909	3.1	Ask applicants why they do not plan to vaccinate young adults on college campuses. In addition, students could be used to help with recruitment	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	6	
PP16004 8	DI	Training CHWs for More Effective Cancer Education and Navigation	Bolin, Jane N	Texas A&M University System Health Science Center	\$300,000	3.1			7	
PP16002 3	EBP- CRC	Optimizing Colorectal Cancer Screening in East Texas	Sauter, Edward	The University of Texas Health Center at Tyler	\$2,299,753	3.3	Recommendation was made in previous application that providing FIT isn't evidence-based for people who are at significant risk for CRC; this isn't consistent with ACS guidelines. Ask how they came up with \$275/colonoscopy	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	8	

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP16003 6	CCE- EBP	Establishing a Comprehensiv e Cancer Prevention and Support Program within Asian American Communities in Houston and Austin Areas of Texas	Sun, Helen	Light and Salt Associatio n	\$1,101,986	3.3	Request that the applicant provides a leadership plan that includes input from the three communities being targeted: Vietnames, Korean, and Filipino	changes not recommended-PRC reveiwed peer review comments and determined they did not impact decision to recommend or impact rank order	9	
PP16002 7	EBP	Improving Service Delivery to Cancer Survivors in Primary Care Settings	Foxhall, Lewis E	The University of Texas M. D. Anderson Cancer Center	\$1,374,127	3.5	Not clear how project will add to what is already happening in clinic. This is a large, complex project and not clear how it will be managed on a daily basis. Budget is weak and justification for some of the positions is lacking	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	10	Recommende d out of score order above one with higher score due to ROI and cancer type
PP16005 1	DI	Dissemination of an Evidence- Based HPV Vaccination Intervention in Community and Clinical Settings	Fernandez , Maria E	The University of Texas Health Science Center at Houston	\$299,778	3.6	List of current awards doesn't specify PD participation; it should be verified that PD isn't overcommitted. Budget seems somewhat personnel heavy and accounts for a	changes not recommended-PRC reviewed peer review comments and determined they did not impact decision to recommend or impact rank order	11	Recommende d out of score order above one with higher score due to type of program

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
							large majority of voerall costs; careful review of personnel and their exact roles and responsibilities and whether or not any of the services are duplicative may be warranted.			
PP16001 1	CCE- EBP	GRACIAS Texas: Genetic Risk Assessment for Cancer in All South Texas	Tomlinson , Gail E	The University of Texas Health Science Center at San Antonio	\$1,500,000	2.7			12	Recommende d but ranked out of score order due to 1) ROI may be limited; large numbers need to be screened to identify at risk pop.
PP16004 6	ЕВР	Using social marketing and mobile school-based vaccination clinics to increase HPV vaccination uptake in highrisk geographic areas	Cuccaro, Paula	The University of Texas Health Science Center at Houston	\$1,499,668	2.2			13	Recommende d but out of score order due to 1) geography- several HPV grants in Harris county, 2) ROI-costs for education vs services

App ID	Mech	App. Title	PD	Org.	Requested Funding	Score	Changes recommended from Peer Review	Review of Recommended Changes from Peer Review	Rank Order Score	Explanation of Rank Order
PP16003	CCE- EBP	Increasing cancer control behaviors among the underserved: A collaboration with Texas 2-1-1 programs	Fernandez , Maria E	The University of Texas Health Science Center at Houston	\$1,499,989	2.4			14	Recommende d but out of score order due to 1) geography- several HPV grants in Harris county, 2) cancer type- availabilty of breast and cervical services 3) ROI-costs for education vs services
				Initial funding (Rank #1- 12)	\$13,247,74 2					
				(Rank #13+14)	\$2,999,657					
				2nd funding	\$16,247,39 9					



CEO Affidavit Supporting Information

FY 2016—Cycle 1
Research Training Awards

Request for Applications



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS RFA R-16-RTA-1

Research Training Awards

Please also refer to the Instructions for Applicants document, which will be posted on March 20, 2015

Application Receipt Opening Date: March 20, 2015 **Application Receipt Closing Date:** May 20, 2015

FY 2016

Fiscal Year Award Period September 1, 2015-August 31, 2016

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RFA VERSION HISTORY

Rev 02/20/15 RFA release

1. ABOUT CPRIT

The state of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the
 potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the state of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The principles and priorities of the Scientific Research program will guide CPRIT staff, peer reviewers, and the Scientific Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs. The program priorities for research adopted by the Oversight Committee include funding projects that address:

- A broad range of innovative, investigator-initiated research projects;
- Prevention and early detection;
- Rare and intractable cancers, including childhood cancers;
- Cancers of importance in Texas;
- Computational biology and analytic methods; and
- Building Infrastructure.

2. RATIONALE

The goal of this award is to facilitate the training of the next generation of outstanding cancer researchers to help ensure that a diverse pool of highly trained scientists is available in adequate numbers and in appropriate research areas to address the state's and the nation's basic, population-based, clinical, and translational cancer research needs. Training is expected to be

directed toward building the broad research competence required to ensure that trainees are prepared to assume leadership roles in cancer research. This award supports the training of highly qualified individuals, both predoctoral and postdoctoral, who have the potential to become productive, independent research scientists or physician-scientists and who intend to pursue careers focused on cancer research.

Committed institutional support is required, especially in the form of superb research opportunities, excellent instruction and mentoring, and state-of-the-art facilities. Trainees are expected to be immersed in a highly interactive and supportive didactic and research program that facilitates research and instruction in cancer-related areas that will contribute to innovative approaches to key problems and will help bring novel solutions and potential therapies into practice. The training environment should be enriched by programmatic elements such as seminars from visiting researchers, journal clubs, internal research seminars, videoconferencing with collaborating institutions (if applicable), and attendance at national and/or international scientific meetings. Each supported trainee is expected to identify an appropriate mentor and/or mentor committee that will be responsible for providing critical teaching, advising, and leadership experience.

In addition to support of PhD and postdoctoral research training, potential opportunities include the following:

- Master's degree—level programs to train clinical investigators. Trainees may be in predoctoral (MD/MS) programs or clinical fellowship positions, or they should have just received their first faculty appointment as an instructor or assistant professor.
- Master's degree—level programs to facilitate trainees' pursuit of research careers as high-level laboratory support personnel. When trained, such individuals would be capable of training others in a laboratory with regard to sophisticated technical issues and of performing research with only modest levels of supervision. CPRIT encourages innovative approaches to training such individuals. Programs whose goals are to produce trainees with a conventional master's degree in a relevant biomedical or related science by successful completion of a relatively modest research project are not appropriate.
- Undergraduate summer research internship programs, particularly those directed at underrepresented minorities.

3. RESEARCH OBJECTIVES

This RFA solicits applications for *integrated institutional research training programs* to support promising individuals who seek specialized training in the area of cancer research. The goals of the Research Training Awards are to attract outstanding predoctoral (PhD or MD/PhD) and postdoctoral trainees committed to pursuing a career in basic, population-based, translational, or clinical cancer research; to expand the skills and expertise of trainees to promote the next generation of investigators and leaders in cancer research; to position most trainees for independent research careers; and to support the development of high-quality, innovative, and creative research that, if successful, could provide the basis for a significant impact on cancer prevention, detection, and/or treatment. Successful applicant institutions are expected to provide trainees with broad access to research opportunities across disciplinary and departmental lines and to maintain high standards for intellectual rigor and creativity.

It is expected that the research training experience will provide the following:

- A strong foundation in research design, methods, and analytic techniques appropriate to the proposed research project;
- The development or enhancement of the supported trainee's ability to conceptualize and think through research problems with increasing independence;
- Experience in conducting, presenting, and publishing independent research;
- Instruction in the responsible conduct of research;
- The opportunity to interact with members of the scientific community at appropriate seminars, scientific meetings, and workshops; and
- A well-conceived career plan to increase the trainee's ability to secure additional support for his or her research.

Individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds are especially encouraged to participate in CPRIT's training programs, and a plan for recruiting such individuals is a requirement for this award. In addition to predoctoral and postdoctoral research training, potential opportunities include master's degree—level programs to train clinical investigators; undergraduate summer research internship programs, particularly those directed at recruitment of underrepresented minorities; and master's degree—level programs to encourage the pursuit of alternative careers in laboratory support positions. Awards will be made for institutional programs; individual fellowship applications will not be considered. CPRIT expects outcomes of

supported activities to directly and indirectly benefit subsequent cancer research efforts, cancer public health policy, or the continuum of cancer care—from prevention to treatment and cure. To fulfill this vision, trainees may pursue any research topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, or cure. Each supported trainee and his or her mentor and institution are jointly responsible for planning, directing, and executing the proposed research training program.

Attracting the finest trainees to Texas laboratories and academic institutions is critically important for the local cancer research enterprises, but it is acknowledged that a significant number of those trained in Texas may ultimately seek positions elsewhere.

4. FUNDING INFORMATION

Applicants may request a maximum of \$800,000 in total costs per year for up to 5 years. Requests for funds to support construction and/or renovation will not be approved under this funding mechanism. State law limits the amount of award funding that may be spent on indirect costs to no more than 5% of the total award amount.

Support may be requested as follows for the various types of trainees in an institutional training program:

- **PhD trainees:** May request support for stipend (up to \$28,000 per year, which may be supplemented with other available funds) and benefits and an allowance per trainee of \$1,000 per year that may be used for travel to scientific meetings if the trainee is making a presentation (oral or poster). Funds for tuition may also be requested (to a maximum of \$6,000 per year). Individual trainees may be supported for up to 4 years, but they cannot be supported by this mechanism until it is clear that their mentor and research program are highly relevant to cancer.
- **MD/PhD trainees:** May request support equal to that of Ph.D. trainees (above). Funds may be used only during the time of research training, not during medical school years.
- **Postdoctoral trainees:** May request NIH-scale salary support plus benefits and an allowance per trainee of \$2,000 per year for travel to scientific meetings. Appointments may be made for up to 3 years. Individuals holding PhD, MD/PhD, or MD degrees are eligible for postdoctoral fellowship support provided that the training supported by CPRIT is for research (basic, population-based, translational, or clinical).

Support may also be requested for following types of institutional training programs:

- Undergraduate summer internship programs: May request up to \$6,000 per trainee for summer stipend and housing allowance.
- Master's degree—level programs to support research careers as laboratory support personnel: May request stipend support (\$28,000 per year) plus benefits. Appointments may be made for up to 2 years. Funds for tuition may also be requested (to a maximum of \$6,000 per year).
- Master's degree—level programs to train clinical investigators: May request \$28,000 per year plus benefits if trainees are predoctoral (eg, an MD/MS training program). Funds may not be used while trainees are in medical school. May request \$50,000 per year plus benefits if trainees are clinical fellows or faculty members. It is anticipated that institutions will supplement stipends for trainees at this level. Funds for tuition may be requested (to a maximum of \$6,000 per year).

5. ELIGIBILITY

- The applicant must be a Texas-based institution of higher education or a component of a university system with appropriately accredited degree-granting training programs (if support is requested for training leading to a degree).
- The Principal Investigator (PI) must have a doctoral degree, including MD, PhD, DDS,
 DMD, DrPH, DO, DVM, or equivalent, and must reside in Texas during the time the research that is the subject of the grant is conducted.
- An institution may submit only 1 new or renewal application under this RFA during this funding cycle. An exception will be made for institutions submitting applications for cancer prevention training; in this case, institutions may submit 1 prevention training program application and 1 additional application in another aspect of cancer research (new or renewal). For the purposes of this RFA, an institution is defined as that component of a university system that has its own president. There must be only 1 PI, but Co-PIs may direct individual components of the overall program described in the application. An institution may apply for as many components of the training program as are appropriate for the institution.

- Trainees with the skills and background necessary to carry out the proposed research training should work with their mentors and other appropriate individuals in the institution to develop individual applications for their own support. These applications are to be submitted to the PI in a form to be determined by the PI and will be evaluated in a manner to be described by the PI.
- All supported trainees must reside in Texas during the time the training program that is the subject of the grant is conducted.
- Trainees may be citizens or noncitizen nationals of the United States or international citizens who hold student visas. All trainees should be officially enrolled in the appropriate training program.
- Excluding summer interns, trainees must have at least a baccalaureate degree and show evidence of both high academic performance in the sciences and keen interest in research in areas of high priority to the participating institution. In addition, trainees who are degree candidates must be enrolled in an accredited program and be sponsored by a mentor for the research component.
- CPRIT funds may be used to supplement funding available from other sources if the pool of trainees is of sufficient size and quality to justify additional support.
- Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the state of Texas, but non— Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PI, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.

- The applicant must report whether the applicant institution or organization, the PI, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in section 11 and section 12. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. RESUBMISSION POLICY

Applicants preparing a resubmission must describe the approach to the resubmission. If a summary statement was prepared for the original application review, applicants are advised to address all noted concerns.

Note: An application previously submitted to CPRIT but not funded may be resubmitted once after careful consideration of the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a fresh Training Plan or modify the original Training Plan and mark the changes. However, all resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

7. RENEWAL POLICY

Applicants preparing a renewal must describe and demonstrate that appropriate/adequate progress has been made on the current funded award to warrant further funding. Publications and manuscripts in press that have resulted from work performed during the initial funded period should be listed in the renewal summary.

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and submit an application. The Co-PI, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (ASO) (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 AM central time on March 20, 2015, and must be submitted by 3 PM central time on May 20, 2015. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

8.1.1. Submission Deadline Extension

The submission deadline may be extended for 1 or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via email to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in <u>section 5</u> will be administratively withdrawn without review.

8.2.1. Abstract and Significance (5,000 characters)

Clearly describe the proposed training program. Explain program goals and provide an outline of the proposed didactic and research training activities and an overview of the institutional infrastructure and commitment. The specific aims of the application must be obvious from the abstract although they need not be restated verbatim from the Research Training Plan. Clearly

address how the proposed program, if successful, will have a major impact on cancer and will increase the number of underrepresented minorities in the field.

Note: It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance statement alone. Therefore, applicants are advised to prepare this section wisely. Applicants should not waste this valuable space by stating obvious facts (eg, that cancer is a significant problem; that better diagnostic and therapeutic approaches are needed urgently; or that the type of cancer of interest to the PI is important, vexing, or deadly). Based on this statement (and the Budget and Justification and Biographical Sketches), applications that are judged to offer only modest contributions to the training of cancer researchers or that do not sufficiently capture the reviewers' interest may be excluded from further peer review (see section 9.1).

8.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer research addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer research, early diagnosis, prevention, or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Do not include any proprietary information in the Layperson's Summary. The Layperson's Summary will also be used by advocate reviewers (section 9.2) in evaluating the significance and impact of the proposed work.

8.2.3. Goals and Objectives

Concisely state the specific goals and objectives to be achieved by the training plan described in the application. Goals and objectives should be listed for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success.

8.2.4. Timeline (1 page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.5. Resubmission Summary (1 page)

Applicants preparing a resubmission must describe the approach to the resubmission. If a summary statement was prepared for the original application review, applicants are advised to address all noted concerns.

Note: An application previously submitted to CPRIT but not funded may be resubmitted once after careful consideration of the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a fresh Training Plan or modify the original Training Plan and mark the changes. However, all resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

8.2.6. Renewal Summary (5 pages)

Applicants preparing a renewal must describe and demonstrate that appropriate/adequate progress has been made on the current funded award to warrant further funding. Please provide a brief summary of the progress of the project, results obtained to date, problems/issues encountered and actions taken, and include information about any publications, patents, and/or economic impact. Information provided should be based around the stated specific aims and goals as set forth in the original Scope of Work as approved.

8.2.7. Research Training Plan (15 pages)

Background: Present the rationale behind the proposed training plan, emphasizing how the proposed project will support the development of dedicated investigators in cancer research.

Program Goals: Concisely state the goals and objectives to be achieved by the research training plan described in the application. These need not be fully repeated (as entered in <u>section 8.2.3</u>), and may only be summarized.

Training Plan: Provide a description of proposed courses/classes, seminars, and opportunities for interaction with other groups and scientists. Describe both formal program requirements and opportunities for professional development. Training in career skills (eg, grantwriting and presentation skills) is strongly encouraged. Elaborate on the research environment and available research facilities and equipment, and discuss the relationship of the proposed research projects to trainees' careers. A training plan must be described for each type of program for which support is requested.

Selection of Trainees and Mentors: Describe the process and major criteria that will be used to select trainees to be supported by this program. Describe the process and major criteria that will be used to select mentors for this program.

PI: Outline the responsibilities of the PI in the overall management, administration, and evaluation of the program. Describe how the PI's scientific background, leadership, and administrative capabilities will enable him or her to coordinate and oversee the proposed research training program. Describe the research training record of the PI and, if applicable, Co-PIs.

Recruitment Plan/Diversity Recruitment: Include a recruitment and retention plan for recruiting trainees from both outside and inside the applicant institution and for attracting trainees from complementary disciplines (eg, from the physical, computational, and engineering sciences) to cancer research. Provide plans for enhancing the diversity of the trainee pool by recruiting from underrepresented groups and a plan for retaining such trainees (this will be an important factor in the evaluation of the application). Applications that do not address recruitment and retention will be considered incomplete.

Responsible Conduct of Research: Describe the plan to provide instruction in the responsible conduct of research, including the rationale, subject matter, appropriateness, format, frequency, and duration of instruction. The amount and nature of faculty participation must be described.

8.2.8. Publications/References

Provide a concise and relevant list of publications/references cited for the application.

8.2.9. Budget and Justification

Provide an outline and justification of the budget for the entire proposed period of support. Allowable costs include trainee stipends (see limits in section 5), benefits, and travel allowances (as indicated in section 5). Tuition (up to a maximum of \$6,000 per year) may be included for those in degree-granting programs. The budget should be based on the number of trainee slots requested for each type of training activity. Justification of the number of trainees requested must be compelling and based on the number of exceptionally well-qualified individuals who are likely to be available and who deserve such support as well as funds currently available from other training programs to support them. An appropriate and modest level of salary support may be requested for the PI, Co-PIs, and administrative staff.

In preparing the requested budget, applicants should be aware of the following:

- Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5% of the total award amount (5.263% of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. So-called grants management and facilities fees (eg, sponsored programs fees; grants and contracts fees; electricity, gas, and water; custodial fees; maintenance fees) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.
- The annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2016 is \$200,000; CPRIT FY 2016 is from September 1, 2015, through August 31, 2016. Salary does not include fringe benefits and/or facilities and administrative (F&A) costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

8.2.10. Biographical Sketches (14-page maximum)

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. A biographical sketch must be provided for the PI and, if applicable, the Co-PI (as required by the online application receipt system), and 2 to 5 additional biographical sketches for key faculty members. Each biographical sketch must not exceed 2 pages.

8.2.11. Current and Pending Support

Describe the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title and a 2-line summary of the goal of the project.

8.2.12. Institutional Support (3 pages)

Each application must be accompanied by a letter of institutional support from the president or provost indicating support and commitment to the training program. The letter could include, but is not limited to, information about laboratory space, shared laboratory facilities and equipment, funds for curriculum development, support for additional trainees in the program, and initiatives to support recruitment of underrepresented minorities. A maximum of 3 pages may be provided.

8.2.13. Previous Summary Statement

If the application is being resubmitted, the summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission. The applicant is not responsible for providing this document.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively rejected without review.

9. APPLICATION REVIEW

9.1. Preliminary Evaluation

To ensure the timely and thorough review of only the most innovative and cutting-edge research training programs with the greatest potential for advancement of cancer research, all eligible applications may be preliminarily evaluated by CPRIT Scientific Research Program panel members for scientific merit and impact.

This preliminary evaluation will be based on a subset of material presented in the application—namely Abstract and Significance, Budget and Justification, and Biographical Sketches. Applications that do not sufficiently capture the reviewers' interest at this stage will not be considered for further review. Such applications will have been judged to offer only modest contributions to the training of cancer researchers and will be excluded from further peer review.

The applicant will be notified of the decision to disapprove the application after the preliminary evaluation stage has concluded. Due to the volume of applications to be reviewed, comments made by reviewers at the preliminary evaluation stage may not be provided to applicants. The preliminary evaluation process will be used only when the number of applications exceeds the capacity of the review panels to conduct a full peer review of all received applications.

9.2. Full Peer Review

Applications that pass preliminary evaluation will undergo further review using a 2-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts as well as advocate reviewers using the criteria listed below. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by Scientific Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC.

The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, chapter 703, sections 703.6 to 703.8.

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

9.3. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, Scientific Review Council members, PIC members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Peer Review Panel members and Scientific Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's website. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, chapter 703, section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: An Oversight Committee Member, a PIC Member, a Scientific Review Panel member, or a Scientific Review Council member. Applicants should note that the CPRIT PIC comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services.

The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

9.4. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.

9.4.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed training program. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed program. Primary criteria include the following:

Primary Review Criteria for New Applications

Overall Evaluation of Training Potential: What is the likelihood that the training program will serve as a sound foundation to enhance a supported trainee's potential for, and commitment to, a productive, independent scientific research career in a cancer-related field?

Research Training Plan: Will the training plan provide trainees with individualized and supervised experiences that will enable them to develop the research skills needed to be independent researchers or physician-scientists? Is the training plan customizable for students from diverse academic backgrounds and differing educational philosophies?

PI and Mentors: Do the PI and mentors have excellent research qualifications (including publications in high-quality journals and peer-reviewed research support) and track records of mentoring that are appropriate for the proposed training program?

Trainees: Are high-quality individuals routinely recruited at the applicant institution's existing training programs? Are the qualifications and interests of these potential trainees appropriate for the training program described by the applicant institution? Are there sufficient numbers of highly meritorious potential trainees to fill the slots requested? Is there a plan to enhance the diversity of trainees by recruiting from underrepresented groups?

Institutional Environment and Commitment to Training: Is there a high-quality institutional environment for the scientific development of trainees? Is there appropriate institutional commitment to fostering training as investigators or physician-scientists? Are the research facilities, resources (eg, equipment, laboratory space, computer time, subject populations), and training opportunities adequate and appropriate?

Primary Review Criteria for Renewal Applications

Overall Evaluation of Training Outcomes and Future Potential: Does the proposed continuation of the program demonstrate a high likelihood of success based on the initial program's results and outcomes? Has the applicant sufficiently described results and findings of the previously funded application? What is the likelihood that the training program will continue to serve as a sound foundation to enhance a supported trainee's potential for, and commitment to, a productive, independent scientific research career in a cancer-related field? Has the program recruited underrepresented minority trainees?

Research Training Plan: Has the training plan provided, and will the plan continue to provide, trainees with individualized and supervised experiences that will enable them to develop the research skills needed to be independent researchers or physician-scientists? Is the training plan customizable for students from diverse academic backgrounds and differing educational philosophies?

PI and Mentors: Do the PI and mentors have excellent research qualifications (including

publications in high-quality journals and peer-reviewed research support) and track records of

mentoring that are appropriate for the proposed training program?

Trainees: Have high-quality individuals been recruited into the training programs? Are the

qualifications and interests of these potential trainees appropriate for the training program

described by the applicant institution? Have there been sufficient numbers of highly meritorious

candidates to fill the available slots? Have efforts been made to enhance the diversity of trainees

by recruiting from underrepresented groups? Has appropriate progress been demonstrated by

trainees?

Institutional Environment and Commitment to Training: Is there a high-quality institutional

environment for the scientific development of trainees? Is there appropriate institutional

commitment to fostering training as investigators or physician-scientists? Are the research

facilities, resources (eg. equipment, laboratory space, computer time, subject populations), and

training opportunities adequate and appropriate?

9.4.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these

criteria potentially question the value of the proposed training program.

Secondary criteria include the following:

Relevance to Cancer Research: Does the proposed training program have a high degree of

direct relevance to cancer research? Does the program include high priority areas of emphasis for

CPRIT (prevention and early detection, rare and intractable cancers, computational biology,

cancers of special interest in Texas)?

Project Leadership: Is the program managed by strong leadership in a position to organize and

manage the proposed training activities?

Responsible Conduct of Research: Does the applicant institution have acceptable plans to

provide instruction in the responsible conduct of research?

Budget: Is the budget appropriate for the proposed work?

Duration: Is the stated duration appropriate for the proposed work?

10. KEY DATES

RFA

RFA release February 20, 2015

Application

Online application opens March 20, 2015, 7 AM central time

Application due May 20, 2015, 3 PM central time

Application review September - October 2015

Award

Award notification November 2015

Anticipated start date March 2016

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in chapter 701, section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. Applicants are advised to review CPRIT's administrative rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in chapter 703, sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, chapter 703, section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed, and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, chapter 703, section 703.11, for specific requirements regarding demonstration of available funding.

13. CONTACT INFORMATION

13.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via email will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding scientific aspects of applications.

Dates of operation: February 20 – May 20, 2015 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time

Wednesday, 8 AM to 4 PM central time

Tel: 866-941-7146

Email: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Senior Manager for Research.

Tel: 512-305-8491

Email: <u>Help@CPRITGrants.org</u>

Website: www.cprit.state.tx.us

Third Party Observer Reports



CPRIT Research Peer Review Observation Report

Report #2015-09-29-RES

Program Name: Academic Research

Panel Name: FY16.1 Clinical & Translational Cancer

Research and Translational Cancer Research

Panel Date: September 29, 2015 Report Date: October 7, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Clinical & Translational Cancer Research and Translational Cancer Research peer review of applications for FY16 funding. The meeting was co-chaired by Richard O'Reilly and Margaret Tempero and held at the Marriott Suites Medical/Market Center in Dallas TX on September 29, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Clinical & Translational Cancer Research and Translational Cancer Research panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and co-chaired by Richard O'Reilly and Margaret Tempero on September 29, 2015.

The independent observer noted the following during our observation:

- Twenty-four applications were discussed within the Research Peer Review Meeting to determine which
 grants would receive CPRIT funding.
- Twenty-six peer review panelists, three advocate reviewers, three CPRIT staff members and five SRA employees were present for the meeting.
 - o Two of the twenty-six peer review panelists participated via teleconference.
- Thirteen conflicts of interest were identified prior to or during the meeting. Applications for nine
 conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest either
 left the room or did not participate telephonically and did not participate in the review of the conflicted
 application.
 - One of the nine conflicts did not sign out on the conflict of interest sign out sheet when leaving the room.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Research Peer Review Observation Report

Report #2015-09-30-RES

Program Name: Academic Research

Panel Name: FY16.1 Cancer Prevention Research

Panel Date: September 30, 2015 Report Date: October 7, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Cancer Prevention Research peer review of applications for FY16 funding. The meeting was chaired by Tom Sellers and held at the Marriott Suites Medical/Market Center in Dallas TX on September 30, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Cancer Prevention Research panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Tom Sellers on September 30, 2015.

The independent observer noted the following during our observation:

- Nineteen applications were discussed within the Research Peer Review Meeting to determine which
 grants would receive CPRIT funding.
- Seventeen peer review panelists, two advocate reviewers, four CPRIT staff members and five SRA
 employees were present for the meeting.
 - One of the seventeen peer review panelists participated via teleconference and for only one application.
- Twenty-one conflicts of interest were identified prior to or during the meeting. Applications for fifteen
 conflicts were discussed during the peer review panel. The reviewers with the conflicts of interest either
 left the room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical
or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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CPRIT Research Peer Review Observation Report

Report #2015-10-01-RES

Program Name: Academic Research

Panel Name: FY16.1 Imaging Technology and

Informatics

Panel Date: October 1, 2015 Report Date: October 7, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Imaging Technology and Informatics peer review of applications for FY16 funding. The meeting was chaired by Sam Gambhir and held at the Marriott Suites Medical/Market Center in Dallas TX on October 1, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Imaging Technology and Informatics panel meeting held inperson. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Sam Gambhir on October 1, 2015.

The independent observer noted the following during our observation:

- Eighteen applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Twenty-one peer review panelists, two advocate reviewers, two CPRIT staff members and five SRA
 employees were present for the meeting.
 - One of the twenty-one peer review panelists participated via teleconference.
- Five conflicts of interest were identified prior to or during the meeting. Applications for two conflicts
 were discussed during the peer review panel. The reviewers with the conflicts of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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CPRIT Research Peer Review Observation Report

Report #2015-10-05-RES

Program Name: Academic Research

Panel Name: FY16.1 Basic Cancer Research 2

Panel Date: October 5, 2015 Report Date: October 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Basic Cancer Research 2 peer review of applications for FY16 funding. The meeting was chaired by Carol Prives and held at the Marriott Suites Medical/Market Center in Dallas TX on October 5, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Basic Cancer Research 2 panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Carol Prives on October 5, 2015.

The independent observer noted the following during our observation:

- Nineteen applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Fifteen peer review panelists, two advocate reviewers, two CPRIT staff members, five SRA employees
 and chair for the Scientific Review Council were present for the meeting.
 - o Two of the fifteen peer review panelists participated via teleconference.
 - One participated for review of only four applications and the other participated as an ad hoc reviewer for one application.
- Two conflicts of interest were identified prior to or during the meeting. Applications for one conflict
 was discussed during the peer review panel. The reviewer with the conflict of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
 - o The reviewer was present when final scores were still visible on projection screen.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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CPRIT Research Peer Review Observation Report

Report #2015-10-06-RES

Program Name: Academic Research

Panel Name: FY16.1 Basic Cancer Research 1

Panel Date: October 6, 2015 Report Date: October 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Basic Cancer Research 1 peer review of applications for FY16 funding. The meeting was chaired by Tom Curran and held at the Marriott Suites Medical/Market Center in Dallas TX on October 6, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Basic Cancer Research 1 panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Tom Curran on October 6, 2015.

The independent observer noted the following during our observation:

- Thirty applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Eighteen peer review panelists, two advocate reviewers, three CPRIT staff members and six SRA
 employees were present for the meeting.
 - One of the eighteen peer review panelists participated via teleconference.
 - One of the two advocate reviewers participated via teleconference.
- Two conflicts of interest were identified prior to or during the meeting. Applications for one conflict
 was discussed during the peer review panel. The reviewer with the conflict of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical
or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

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CPRIT Research Peer Review Observation Report

Report #2015-10-07-RES

Program Name: Academic Research

Panel Name: FY16.1 Cancer Biology

Panel Date: October 7, 2015 Report Date: October 13, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Cancer Biology peer review of applications for FY16 funding. The meeting was chaired by Peter Jones and held at the Marriott Suites Medical/Market Center in Dallas TX on October 7, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Cancer Biology panel meeting held in-person. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Peter Jones on October 7, 2015.

The independent observer noted the following during our observation:

- Twenty-two applications were discussed within the Research Peer Review Meeting to determine which grants would receive CPRIT funding.
- Fifteen peer review panelists, two advocate reviewers, two CPRIT staff members and five SRA
 employees were present for the meeting.
 - o Two of the fifteen peer review panelists participated via teleconference.
- Seven conflicts of interest were identified prior to or during the meeting. Applications for five conflicts
 were discussed during the peer review panel. The reviewers with the conflicts of interest either left the
 room or did not participate telephonically and did not participate in the review of the conflicted
 application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.



CPRIT Scientific Review Council Meeting Observation Report

Report #2015-10-23-RES

Program Name: Academic Research

Panel Name: FY16.1 Scientific Review Council

Meeting

Panel Date: October 23, 2015 Report Date: October 27, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Scientific Review Council Meeting peer review of applications for FY16 funding. The meeting was chaired by Richard Kolodner and held via teleconference on October 23, 2015.

Panel Observation Objectives and Scope

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



The independent observer participated in the Scientific Review Council Meeting held via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Richard Kolodner on October 23, 2015.

The independent observer noted the following during our observation:

- Over the course of the call, a review of the scoring for the 65 recommended applications was completed to ensure that they would in fact be recommended for funding. A score cut-off was reinforced by the panel as to which applications will move forward.
- Six peer review panelists, two CPRIT staff members and one SRA employee were present for the meeting.
- No conflicts of interest were identified prior to or during the meeting.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Academic Research Cycle 16.1 Applications (Academic Research Cycle 16.1 Awards Announced at November 19, 2015 Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Cycle 16.1 include Individual Investigator Research Awards, Individual Investigator Research Awards for Prevention and Early Detection, Individual Investigator Research Awards for Cancer in Children and Adolescents, Individual Investigator Research Awards for Computational Biology, and Research Training Awards. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
RP160183pe/ RP160183	Davies, Michael	The University of Texas M. D. Anderson Cancer Center	McMahon, Martin
RP160471pe/ RP160471	Draetta, Giulio	The University of Texas M. D. Anderson Cancer Center	Courtneidge, Sara
RP160013pe/ RP160013	Kundra, Vikas	The University of Texas M. D. Anderson Cancer Center	Riddell, Stanley; Engelhard, Victor
RP160188pe/ RP160188	Schluns, Kimberly	The University of Texas M. D. Anderson Cancer Center	Engelhard, Victor
RP160482pe/ RP160482	Heimberger, Amy	The University of Texas M. D. Anderson Cancer Center	Engelhard, Victor
RP160577pe/ RP160577	Poojary, Venuprasad	Baylor Research Institute	Cooney, Kathleen
RP160497pe/ RP160497	Krishnan, Sunil	The University of Texas M. D. Anderson Cancer Center	Berbeco, Ross
RP160589	Chapkin, Robert	Texas AgriLife Research	Fearon, Eric; Greene, Geoffrey

Application ID	Applicant	Institution	Conflict Noted
RP160015	Ness, Roberta	The University of Texas	Haiman, Christopher;
KI 100013	rvess, reocetta	Health Science Center at	Kushi, Lawrence
		Houston	Rushi, Lawrence
RP160030	Gerber, David	The University of Texas	Barlow, William
KI 100050	Gerber, Buvia	Southwestern Medical	Darrow, william
		Center	
RP160097	Spitz, Margaret	Baylor College of	Martinez, Maria
100077	Spitz, Margaret	Medicine	, wara
RP160145	Bast, Robert	The University of Texas	Kushi, Lawrence; Li,
	,	MD Anderson Cancer	Christopher
		Center	P
Applications	Not Recommended for	PIC or Oversight Commi	ttee Consideration
RP160117pe/	Chen, Benjamin	The University of Texas	Bart Williams
RP160117*	Chen, Benjamin	Southwestern Medical	Dart Williams
111 100117		Center	
RP160472pe	Cox, Marc	The University of Texas	McMahon, Martin
r ·	,	at El Paso	,
RP160079pe	Saikumar, Pothana	The University of Texas	Sonenberg, Nahum
•	ŕ	Health Science Center at	J.
		San Antonio	
RP160113pe	Davis, Anthony	The University of Texas	Tomkinson, Alan;
		Southwestern Medical	Chazin, Walter
		Center	
RP160304pe	Denicourt, Catherine	The University of Texas	Petrini, John
		Health Science Center at	
		Houston	
RP160335pe/	Wang, Bin	The University of Texas	Matthew Weitzman
RP160335*		M. D. Anderson Cancer	
DD4 (02=1	D 4 D 11	Center	TD 1: 41
RP160374pe	Boothman, David	The University of Texas	Tomkinson, Alan
		Southwestern Medical	
DD1/0/11mg	Sahiff Daahal	Center Paylor Callaga of	Datrini John
RP160611pe	Schiff, Rachel	Baylor College of Medicine	Petrini, John
RP160621pe	Latham, Michael	Texas Tech University	Petrini, John
RP160506pe	Aiden, Erez	Baylor College of	Bernstein, Bradley;
111 100300рс	1114011, 11101	Medicine Medicine	Hahn, William
RP160537pe	Kim, Min	The Methodist Hospital	Wahl, Geoffrey
111 1000 / pc		Research Institute	, Storing
RP160477pe	Hassan, Manal	The University of Texas	Petersen, Gloria;
P		M. D. Anderson Cancer	Martinez, Maria
		Center	
	I.	1	1

Application ID	Applicant	Institution	Conflict Noted
RP160076pe	Jha, Mithilesh	The University of Texas Health Science Center at San Antonio	Hochster, Howard
RP160143pe/ RP160143	Nurieva, Roza	The University of Texas M. D. Anderson Cancer Center	Stadler, Walter; Engelhard, Victor
RP160176pe/ RP160176*	Sharma, Padmanee	The University of Texas M. D. Anderson Cancer Center	Riddell, Stanley
RP160230pe	Trippier, Paul	Texas Tech University Health Sciences Center	Balk, Steven
RP160336pe/ RP160336*	Diab, Adi	The University of Texas M. D. Anderson Cancer Center	Engelhard, Victor
RP160359pe	Bhattacharya, Pratip	The University of Texas M. D. Anderson Cancer Center	Haas-Kogan, Daphne
RP160580pe	Biros, George	The University of Texas at Austin	Mitchell, Duane
RP160645pe/ RP160645*	Jo, Javier	Texas Engineering Experiment Station	Liu, Jonathan; Sutcliffe, Julie
RP160648pe/ RP160648*	Chen, Wei	The University of Texas at Arlington	Zinn, Kurt
RP160222	Rao, Hai	The University of Texas Helath Science Center at San Antonio	Carol Prives
RP160373	Naora, Honami	The University of Texas MD Anderson Cancer Center	Greene, Geoffrey
RP160395*	Lee, Min Gyu	The University of Texas MD Anderson Cancer Center	Belinksy, Steven
RP160535	Kang, Min	Texas Tech University Health Sciences Center	DeClerck, Yves
RP160567*	Zhang, Michael	The University of Texas at Dallas	Lowlor, Elizabeth
RP160168	Felini, Martha	University of North Texas Health Science Center at Fort Worth	Olshan, Andrew
RP160224	Schick, Vanessa	The University of Texas Health Science Center at Houston	Brandon, Thomas

Application ID	Applicant	Institution	Conflict Noted
RP160354*	Stingo, Francesco	The University of Texas MD Anderson Cancer Center	Barlow, William; Li, Christopher; Peterson, Gloria
RP160408*	Shen, Qiang	The University of Texas MD Anderson Cancer Center	Kumar, Nagi
RP160470	Valerio, Melissa	The University of Texas Health Science Center at Houston	Kushi, Lawrence
RP160499*	Minnix, Jennifer	The University of Texas MD Anderson Cancer Center	Brandon, Thomas; Schnoll, Robert
RP160527	Hanash, Samir	The University of Texas MD Anderson Cancer Center	Barlow, William; Li, Christopher; Mucci, Lorelei
RP160554	Bondy, Melissa	Baylor College of Medicine	Haiman, Christopher; Martinez, Maria
RP160587	Wetter, David	Rice University	Brandon, Thomas
RP160525*	Jiang, Ning	The University of Texas at Austin	Press, Oliver; Riddell, Stanley
RP160540	Reynolds, Charles	Texas Tech University Health Sciences Center	Grupp, Stephen; Kast, W. Martin;
RP160466	Yuan, Baohong	University of Texas at Arlington	Zinn, Kurt

De-Identified Overall Evaluation Scores

Research Training Awards

Academic Research Cycle 16.1

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within the Individual Investigator Research Awards mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

This comprehensive list of Individual Investigator Research Awards de-identified application scores created for the purpose of this CEO affidavit packet combines the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not.

Application ID	Final Overall Evaluation Score
RP160157*	1.2
RP160283*	1.9
RP160097*	2.1
RP160015*	2.1
ta	2.9
tb	3.0
tc	3.1
td	3.3
te	3.5
tf	3.8
tg	3.9
th	4.7
ti	5.0

^{* =} recommended for funding

Final Overall Evaluation Scores and Rank Order Scores





Ludwig Institute for Cancer Research Ltd October 29, 2015

Richard D. Kolodner Ph.D.

Director, San Diego Branch

Head, Laboratory of Cancer Genetics San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

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T 858 534 7804 **F** 858 534 7750

Mr. Pete Geren

Oversight Committee Presiding Officer Cancer Prevention and Research Institute of Texas Via email to pgcprit@sidrichardson.org

Mr. Wayne R. Roberts Chief Executive Officer Cancer Prevention and Research Institute of Texas Via email to wroberts@cprit.state.tx.us

Dear Mr. Geren and Mr. Roberts,

In reviewing the list of recommended applications, we were made aware of one minor error in scoring. Application RP160268 was assigned a score of 2.6 in the list, and the actual score should be 2.7. This recommended application was initially placed in row 41 and now appears in row 44. The change of score is reflected in the attached revised list. This does not change the outcome of the SRC recommendation.

Sincerely yours,

Richard D. Kolodner, Ph.D.

Chair, CPRIT Scientific Review Council





Ludwig Institute for Cancer Research Ltd October 29, 2015

Richard D. Kolodner Ph.D.

Director, San Diego Branch

Head, Laboratory of Cancer Genetics San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

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Mr. Pete Geren Oversight Committee Presiding Officer Cancer Prevention and Research Institute of Texas Via email to pgcprit@sidrichardson.org

Mr. Wayne R. Roberts Chief Executive Officer Cancer Prevention and Research Institute of Texas Via email to wroberts@cprit.state.tx.us

Dear Mr. Geren and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for the Individual Investigator Research Awards (IIRA), Individual Investigator Research Awards for Computational Biology (IIRACB), Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA), Individual Investigator Research Awards for Prevention and Early Detection (IIRAP), Research Training Awards (RTA), and Research Training Awards - Renewal (RTA-R) grant mechanisms. The SRC met on Friday, October 23, 2015 to consider the applications recommended by the peer review panels following their meetings that were held September 29 - October 7, 2015. During the SRC discussion, it was determined that the success rates (percentage of the number recommended/number reviewed) for four panels were much higher than the rates for the other three panels and higher than the historical approval rates. It was suggested that these four panels reduce their success rates to fall in line with the other panels, and all chairs agreed to the scoring adjustments. This resulted in some applications not being recommended for grant awards that received scores equal to or more favorable than some applications that were recommended for grant awards. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded after adjustments were made based on success rates.

Recommended funding amounts and the overall evaluation score are stated for each grant application. The SRC accepted the recommendations of the peer review panels concerning adjustments to three grant applications. These adjustments with justifications are listed at the end of the list of recommended projects. The total amount for the applications recommended is \$62,761,270.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.





Sincerely yours,

Richard D. Kolodner, Ph.D.

Chair, CPRIT Scientific Review Council

Attachment

Rank	App ID	Organization/Company	Application Title	Award Amount	Mech.	Overall Score
Kank	App ID	* *		Amount		Score
	DD1 (0157	The University of Texas	Cancer Intervention and Prevention	Ф2 002 250	RTA-	1.0
1	RP160157	Southwestern Medical Center	Discoveries Program	\$3,993,250	Renewal	1.2
			Decoding Cellular Heterogeneity of			
2	RP160192	Baylor College of Medicine	Malignant Glioma	\$899,701	IIRA	1.3
			Protein Truncation Mutations in WIP1:			
3	RP160451	Baylor College of Medicine	Effects on Cancer and Hematopoiesis	\$900,000	IIRA	1.5
			Development of Therapeutics			
			Targeting Truncated Adenomatous			
			Polyposis Coli (APC) as a Novel			
		The University of Texas	Prevention and Intervention Strategy			
4	RP160180	Southwestern Medical Center	for Colorectal Cancer	\$900,000	IIRA	1.8
			A novel epigenetic reader as			
		The University of Texas M. D.	therapeutic target in MLL-translocated		IIRACC	
5*	RP160237	Anderson Cancer Center	pediatric leukemias	\$900,000	A	1.8
			Baylor College of Medicine			
			Comprehensive Cancer Training		RTA-	
6	RP160283	Baylor College of Medicine	Program	\$3,986,268	Renewal	1.9
		The University of Texas				
_		Health Science Center at San			IIRACC	
7	RP160487	Antonio	Cytokine signaling in Ewing sarcoma	\$1,200,000	A	1.9
			A Randomized Controlled Trial (RCT)			
			of Patient Navigation for Lung Cancer			
	DD1 60000	The University of Texas	Screening in an Urban Safety-Net	01.402 51 5	110 : 5	
8	RP160030	Southwestern Medical Center	System	\$1,492,616	IIRAP	1.9
			Promoting The Functions of Memory T			
9	RP160384	Baylor College of Medicine	cells for Adoptive T cell Therapy	\$887,676	IIRA	1.9
			Role of Long Non-Coding RNAs in			
			Breast Cancer: Identification,			
		The University of Texas	Characterization, and Determination of			
10	RP160318	Southwestern Medical Center	Molecular Functions	\$886,652	IIRA	2.0

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			Arylhydrocarbon receptor mediated			
			modulation of colorectal cancer by			
11	RP160589	Texas AgriLife Research	microbiota metabolites	\$890,840	IIRAP	2.0
- 11	Kt 100507	Texas rigitalite Research	Pediatric Radiation Oncology with	\$670,040	IIIQ II	2.0
		The University of Texas	Movie Induced Sedation Effect		IIRACC	
12**	RP160190	Southwestern Medical Center	(PROMISE)	\$900,000	A	2.0
12	100170	The University of Texas M. D.	Amplified gold nanoparticle-mediated	Ψ>00,000	7.1	2.0
13	RP160497	Anderson Cancer Center	radiosensitization of tumors	\$899,309	IIRA	2.0
13	KI 100497	Anderson Cancer Center	Imaging-based quantitative analysis of	\$699,509	ШХА	2.0
			vascular perfusion and tissue			
		The University of Texas M. D.	oxygenation to improve therapy of			
14	RP160229	Anderson Cancer Center	hepatocellular carcinoma	\$885,901	IIRA	2.0
11	10022	7 maerson cancer center	Molecular Mechanism of NLRP12-	φοσο,,, στ	11101	2.0
		The University of Texas	mediated Regulation of Colorectal			
15	RP160169	Southwestern Medical Center	Cancer	\$897,707	IIRA	2.1
		The University of Texas	DIS3L2 in Childhood Wilms Tumor:	, , , , , ,	IIRACC	
16***	RP160249	Southwestern Medical Center	Mechanism to Medicines	\$1,200,000	A	2.1
10	100249	Southwestern Medical Center	Carbamoyl Phosphate Synthase-1: A	ψ1,200,000	F 1	۷.1
		The University of Texas	new metabolic liability in non-small			
17	RP160089	Southwestern Medical Center	cell lung cancers	\$900,000	IIRA	2.1
17	100000	The Methodist Hospital	De-Orphanizing TLX: Implications for	Ψ>00,000	11101	2.1
18	RP160501	Research Institute	Glioblastomas	\$878,969	IIRA	2.1
10	KI 100301		Gilobiastomas	\$676,909	IIIA	2.1
10	DD1 (0 (22	The University of Texas		#20 2 770	HD 4 GD	2.1
19	RP160622	Southwestern Medical Center	Computational live cell histology	\$392,779	IIRACB	2.1
			Cancer Prevention Post-Graduate			
20	RP160097	Davier Callege of Medicine	Training Program in Integrative	\$2.096.900	RTA	2.1
20	KF 100097	Baylor College of Medicine The University of Texas	Epidemiology Collaborative Training of a New Cadre	\$2,986,890	KIA	2.1
		Health Science Center at	of Innovative Cancer Prevention		RTA-	
21	RP160015	Houston	Researchers	\$4,000,000	Renewal	2.1
21	KI 100013			\$4,000,000	Renewai	2.1
22	DD160240	The University of Texas	The role of the Lats kinases in	\$000 500	IID A	2.2
22	RP160340	Southwestern Medical Center	sarcomatoid renal cell carcinoma	\$899,598	IIRA	2.2
			Exploiting molecular and metabolic			
		The University of Texas M. D.	dependencies to optimize personalized			
23	RP160183	Anderson Cancer Center	therapeutic approaches for melanomas	\$900,000	IIRA	2.2
			Understanding Biological and Physical			
		m	Factors Affecting Response to Proton			
2.4	DD1 (0222	The University of Texas M. D.	Therapy to Improve its Clinical	4070 272	IID 4	2.2
24	RP160232	Anderson Cancer Center	Effectiveness	\$879,362	IIRA	2.2
			Role of Cohesin in Hematopoiesis and		IID A CC	
25	DD160022	Dealer Cellege - CM- Histor	Myeloid Leukemia in Children with	¢1.005.639	IIRACC	2.2
25	RP160022	Baylor College of Medicine	Down Syndrome	\$1,905,638	A	2.2
		The University of Texas M. D.	Mechanisms and targeting strategies for			
26	RP160242	Anderson Cancer Center	SWI/SNF mutations in cancer	\$900,000	IIRA	2.3
			Targeting the undruggable: a first-in-			
	DD160446	The University of Texas	class inhibitor of the HIF-2	# 000 115	TIP :	2.2
27	RP160440	Southwestern Medical Center	transcription factor	\$899,412	IIRA	2.3

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28	RP160145	The University of Texas M. D. Anderson Cancer Center	Early Detection of Ovarian Cancer with Tumor Associated Proteins and Autoantibodies	\$1,497,595	IIRAP	2.3
29	RP160013	The University of Texas M. D. Anderson Cancer Center	Visualizing T-cell trafficking	\$900,000	IIRA	2.3
30	RP160019	The University of Texas M. D. Anderson Cancer Center	An Adaptive Personalized Clinical Trial using a Patient-Derived Xenograft Strategy to Overcome Ibrutinib Resistance in Mantle Cell Lymphoma	\$841,606	IIRA	2.3
31	RP160051	Texas A&M University System Health Science Center	Improving contrast for antibody-based tumor detection using PET	\$887,134	IIRA	2.3
32	RP160023	The University of Texas M. D. Anderson Cancer Center	Investigating the genetic and molecular mechanisms underlying RAS/ERK substrate network Novel tumorigenic mechanisms of the	\$900,000	IIRA	2.4
33	RP160211	The University of Texas Southwestern Medical Center	LKB1 tumor suppressor in endometrial and cervical cancer	\$896,653	IIRA	2.4
34	RP160319	The University of Texas Southwestern Medical Center	Role of PARP-1 in Estrogen Receptor Enhancer Function and Gene Regulation Outcomes in Breast Cancers	\$884,315	IIRA	2.4
35	RP160124	The University of Texas Health Science Center at San Antonio	Chemoprevention of Colon Cancer by Anti-inflammatory Blockade Using Neem	\$899,617	IIRAP	2.4
36	RP160188	The University of Texas M. D. Anderson Cancer Center	Regulation of infiltration and function of tumor-resident CD8 T cells by IL-15	\$828,060	IIRA	2.4
37	RP160255	The University of Texas Southwestern Medical Center	Structural and Functional Analyses of the Spindle Checkpoint	\$900,000	IIRA	2.5
38	RP160307	The University of Texas Southwestern Medical Center	Targeting Metastatic Pathways	\$900,000	IIRA	2.5
39	RP160517	The University of Texas M. D. Anderson Cancer Center	Exosomal DNA as a surrogate biomarker for early diagnosis and therapeutic stratification in pancreatic cancer	\$891,938	IIRA	2.5
40	RP160345	Baylor College of Medicine	Engineering T cells to ensure specificity for tumor cells and their environment	\$900,000	IIRA	2.5
41	RP160482	The University of Texas M. D. Anderson Cancer Center	Nanoparticle Targeted STAT3 Immune Expression Clinical Safety and Efficacy of Third	\$888,429	IIRA	2.6
42	RP160121	The University of Texas M. D. Anderson Cancer Center	party, fucosylated, cord blood derived regulatory T cells to prevent graft versus host disease	\$900,000	IIRA	2.6
43	RP160520	The University of Texas Southwestern Medical Center	Effect of Chest Radiation Therapy on Cardiomyocyte Turnover	\$897,570	IIRAP	2.6
44	RP160268	The University of Texas Southwestern Medical Center	DNA damage-induced small non- coding RNAs: mechanism and their role in cancer development	\$900,000	IIRA	2.7

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	ı	Г	T			
			Integrin-mediated IL-18 signaling in			
		The University of Texas	the prevention and treatment of			
		Health Science Center at San	inflammation-associated colorectal			
45	RP160512	Antonio	cancer	\$859,620	IIRA	2.7
			A novel function of Itch in controlling			
			IL-17-induced inflammation in colon			
46	RP160577	Baylor Research Institute	cancer	\$900,000	IIRA	2.7
			Optimizing therapeutic strategies			
		The University of Texas at	against lung cancer using Multi-			
47	RP160617	Dallas	Modality Imaging	\$899,999	IIRA	2.7
			Characterization and pharmacological			
		The University of Texas	targeting of the oncogenic activity of			
48	RP160493	Southwestern Medical Center	Jumonji enzymes	\$899,997	IIRA	2.8
			The CTC Circulator Phenotype:	Í		
			Insights into Mechanisms of Breast			
49	RP160054	Baylor College of Medicine	Cancer Dormancy	\$884,332	IIRA	2.9
49	KF 100034	The University of Texas	Regulation of tumor aggressiveness and	\$664,332	IINA	2.9
		Health Science Center at	immune suppression in lung			
50	DD160225		adenocarcinoma	000 000	IID A	2.0
50	RP160235	Houston	1	\$900,000	IIRA	2.9
			Radiogenomic Screen to Identify Novel			
			Proliferation-associated Glioblastoma			
			Genomic Therapeutic Targets:			
5.1	DD1 601 50	The University of Texas M. D.	Discovery and Mechanistic Validation	#00 7.637	IID 4	2.0
51	RP160150	Anderson Cancer Center	Study	\$897,627	IIRA	3.0
			High resolution imaging for early and			
52	RP160460	Rice University	better detection of bladder cancer	\$873,765	IIRAP	3.0
		The University of Texas M. D.	Identifying new epigenetic	·		
53	RP160471	Anderson Cancer Center	vulnerabilities in pancreatic cancer	\$900,000	IIRA	3.1
- 55	10 100 1/1	- Indiana Canton Conton	Systematic identification of small	Ψ>00,000	11141	5.1
			molecule inhibitors that manipulate			
54	RP160462	Baylor College of Medicine	telomerase activities	\$898,288	IIRA	3.2
JT	100402	Buylor Conege of Wicdichie	The role of Prdm16 and histone H3	\$676,266	шил	J.L
			lysine 9 methyltransferase complex in			
55	RP160035	Baylor College of Medicine	MDS	\$872,157	IIRA	3.2
33	KI 100033	Daylor College of Medicille	MIDS	\$6/4,13/	ШХА	3.4

^{*}RP160237 - The peer review panel recommended reducing the budget to \$300,000 per year for 3 years for a total of \$900,000 based on the scope and depth of the work proposed.

^{**}RP160190 - The peer review panel recommended not funding Aim 4 (Pilot prospective clinical trial) and reducing the budget to \$300,000 per year for 3 years for a total of \$900,000. The final score was based on revised scope with full deletion of Aim 4.

^{***}RP160249 - The peer review panel recommended that given the absence of a clinical trial, the budget should be reduced to \$300,000 per year for 4 years for a total of \$1,200,000.





Success Rate by Panel				
Peer Review	Success	Score		
Panel	Rate	Cutoff		
BCR1	10%	2.3		
BCR2	11%	3.2		
СВ	9%	3.2		
CPR	9%	2.4		
CTCR/TCR	13%	2.7		
ITI	11%	3.0		

Success Rate by Mechanism vs. Total Reviewed					
Mechanism	Success Rate	# Recommended			
IIRA	11%	39/347			
IIRACB	2%	1/50			
IIRACCA	11%	5/44			
IIRAP	13%	6/44			
RTA	14%	1/7			
RTA-R	50%	3/6			
Overall	11%	55/498			

Percent of Applications Recommended by						
Mechai	Mechanism vs. Total Recommended					
Mechanism	# Recommended	Percentage				
IIRA	39/55	71%				
IIRACB	1/55	2%				
IIRACCA	5/55	9%				
IIRAP	6/55	11%				
RTA	1/55	2%				
RTA-R	3/55	5%				
Overall	55/55	100%				



CEO Affidavit Supporting Information

FY 2016—Cycle 2 & 3
Recruitment of Established Investigators

Request for Applications



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-16-REI-1

Recruitment of Established Investigators

Please also refer to the Instructions for Applicants document, which will be posted on June 22, 2015

Application Receipt Dates:

June 22, 2015-June 20, 2016

FY 2016

Fiscal Year Award Period September 1, 2015-August 31, 2016

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RFA VERSION HISTORY

Rev 6/22/15 RFA release

Rev 9/11/15 Revised Section 5 – Eligibility

• Revised language to indicate that a candidate who has already accepted a position at the recruiting institution prior to the time that the Scientific Review Council recommends the candidate for a recruitment award is not eligible for a recruitment award. Also clarification was added indicating that "if a position is offered to the candidate during the period following the Scientific Review Council's recommendation but prior to the Oversight Committee's final approval, the institution does so at its own risk. There is no guarantee that the recruitment award will be approved by the Oversight Committee."

1. ABOUT CPRIT

The state of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the state of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The principles and priorities of the Scientific Research program will guide CPRIT staff, peer reviewers, and the Scientific Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs. The program priorities for research adopted by the Oversight Committee include funding projects that address:

- A broad range of innovative, investigator-initiated research projects;
- Prevention and early detection;
- Rare and intractable cancers, including childhood cancers;
- Cancers of importance in Texas;
- Computational biology and analytic methods; and
- Infrastructure Development

2. RATIONALE

The aim of this award mechanism is to bolster cancer research in Texas by providing financial support to attract world-class research scientists with distinguished professional careers to Texas universities and cancer research institutes to establish research programs that add research talent to the state. This award will support established academic leaders whose body of work has made an outstanding contribution to cancer research. Awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research, thereby advancing cancer research efforts and promoting economic development in the state of Texas. The recruitment of outstanding scientists will greatly enhance programs of scientific excellence in cancer research and will position Texas as a leader in the fight against cancer.

Applications may address any research topic related to cancer biology, causation, prevention, detection or screening, or treatment. However, special consideration will be given to candidates with research programs addressing CPRIT's priority areas for research. These include Prevention and Early Detection; Computational Biology and Analytic Methods; Intractable Cancers (brain, lung, liver, pancreas) and Rare Cancers (<15,000 new cases per year), including Childhood, Adolescent and Young Adult Cancers; Population Disparities and Cancers of Particular Importance in Texas (e.g., liver, cervical and lung).

3. RECRUITMENT OBJECTIVES

The goal of this award mechanism is to recruit exceptional faculty to universities and/or cancer research institutions in the state of Texas. This award honors outstanding senior investigators with proven track records of research accomplishments combined with excellence in leadership and teaching. All candidates should be recognized research or clinical investigators, held in the highest esteem by professional colleagues nationally and internationally, whose contributions have had a significant influence on their discipline and, likely, beyond. They must have clearly established themselves as exemplary faculty members with exceptional accomplishments in teaching and advising and/or basic, translational, population-based, or clinical cancer research activities. It is expected that the candidate will contribute significantly to and have a major impact on the institution's overall cancer research initiative. Candidates will be leaders capable of initiating and developing creative ideas leading to novel solutions related to cancer detection,

diagnosis, and/or treatment. They are also expected to maintain and lead a strong research group and have a stellar, high-impact publication portfolio, as well as continue to secure external funding. Furthermore, recipients will lead and inspire undergraduate and graduate students interested in pursuing research careers and will engage in collegial and collaborative relationships with others within and beyond their traditional discipline in an effort to expand the boundaries of cancer research.

Funding will be given for exceptional candidates who will continue to develop new research methods and techniques in the life, population-based, physical, engineering, or computational sciences and apply them to solving outstanding problems in cancer research that have been inadequately addressed or for which there may be an absence of an established paradigm or technical framework. Ideal candidates will have specific expertise in cancer-related areas needed to address an institutional priority. Candidates should be at the career level of a full professor or equivalent. This funding mechanism considers expertise, accomplishments, and breadth of experience as vital metrics for guiding CPRIT's investment in that person's originality, insight, and potential for continued contribution. Relevance to cancer research and to CPRIT's priority areas are important evaluation criteria for CPRIT funding

Unless prohibited by policy, the institution is also expected to bestow on the newly recruited faculty member the prestigious title of "CPRIT Scholar in Cancer Research," and the faculty member should be strongly encouraged to use this title on letterhead, business cards, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

4. FUNDING INFORMATION

This is a 5-year award and is not renewable. Grant support will be awarded based upon the breadth and nature of the research program proposed. Grant funds of up to \$6 million (total costs) for the 5-year period may be requested. Exceptions to this limit will be entertained only if there is compelling written justification. The award request may include indirect costs of up to 5% of the total award amount (5.263% of the direct costs). CPRIT will make every effort to be flexible in the timing for disbursement of funds; recipients will be asked at the beginning of each year for an estimate of their needs for the year. Funds may not be carried over beyond 5 years. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if

very well justified. **Grant funds may be used for salary support of this candidate but may not be used to construct or renovate laboratory space.** Consistent with the statutory mandate that the recipient institution demonstrate that it has funds equivalent to one-half of the total grant award amount dedicated to the individual recruited, a total institutional commitment of 50% of the total award will be required. The institutional commitment can be made on a year-by-year basis and may be fulfilled by demonstrating funds dedicated to salary support <u>and endowment</u> for the individual recruited as well as expenses for research support, laboratory renovation, and/or relocation to Texas. Grant funding from other sources that the recruited individual may bring with him or her to the institution may also be counted toward the amount necessary for the institutional commitment. No annual limit on the number of potential award recipients has been set.

Note: Depending on the availability of funds, nominations submitted in response to this RFA during the current receipt period may be announced and awarded either in the current fiscal year (prior to August 31) or in the first quarter of the next fiscal year (starting September 1).

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism.
- Candidates must be nominated by the president, provost, vice president for research, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.
- A candidate may be nominated by only 1 institution. If more than 1 institution is
 interested in a given candidate, negotiations as to which institution will nominate him or
 her must be concluded before the nomination is made. There is no limit to the number of
 applications that an institution may submit during a review cycle.
- A candidate who has already accepted a position at the recruiting institution prior to the time that the Scientific Review Council recommends the candidate for a recruitment award is not eligible for a recruitment award, as an investment by CPRIT is obviously not

necessary. No award is final until approved by the Oversight Committee at a public meeting. However, in recognition of the timeline involved with recruiting highly sought-after candidates who are often considering multiple offers, CPRIT's academic research program staff will notify the nominating institution of the Scientific Review Council's recommendation following the Review Council meeting. If a position is offered to the candidate during the period following the Scientific Review Council's recommendation but prior to the Oversight Committee's final approval, the institution does so at its own risk. There is no guarantee that the recruitment award will be approved by the Oversight Committee.

- The candidate must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and reside in Texas for the duration of the appointment. The candidate must devote at least 70% time to research activities. Candidates whose major responsibilities are clinical care, teaching or administration are not eligible.
- At the time of the application, the candidate should hold an appointment at the rank of professor (or equivalent) at an accredited academic institution, research institution, industry, government agency, or private foundation not primarily based in Texas. The candidate <u>must not</u> reside in Texas at the time the application is submitted.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT. Prior to final approval of an award, the candidate must provide the same certification.
- An applicant is not eligible to receive a CPRIT grant award if the applicant nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member. Prior to final approval of an award, the candidate must provide the same certification.
- The applicant must report whether the applicant institution or organization, the nominator, or other individuals who contribute to the execution of the proposed project in

a substantive, measurable way, whether or not the individuals will receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application. Prior to final approval of an award, the candidate must provide the same certification.

CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in Section 10 and Section 11. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. RESUBMISSION POLICY

Resubmissions will not be accepted for the Recruitment of Established Investigators award mechanism. Any nomination for the Recruitment of Established Investigators that was previously submitted to CPRIT and reviewed but was not recommended for funding may not be resubmitted. If a nomination was administratively rejected prior to review, it can be resubmitted in the following cycles.

7. RESPONDING TO THIS RFA

7.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted.

Candidates must be nominated by the institution's president, provost, vice president for research, or appropriate dean. The individual submitting the application (nominator) must create a user account in the system to start and submit an application. Furthermore, the Authorized Signing

Official (ASO), who is the person authorized to sign and submit the application for the organization, and the Grants Contract/Office of Sponsored Projects Official, who is the individual who will manage the grant contract if an award is made, also must create a user account in CARS.

Applications will be accepted on a continuous basis throughout the remainder of FY16. In order to manage the timely review of nominations, it is anticipated that applications submitted by 11:59 p.m. on the 20th day of each month will be reviewed by the 15th day of the following month. For an application to be considered for review during the monthly cycle, that application must be submitted on or before 11:59 p.m. CPRIT will not extend the submission deadline. During periods when CPRIT does not receive an adequate number of applications, the review may be extended into the following month. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

7.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in <u>Section 5</u> will be administratively withdrawn without review.

7.2.1. Summary of Nomination (2,500 characters)

Provide a brief summary of the nomination. Include the candidate's name, organization from which the candidate is being recruited, and also the department and/or entity within the nominator's organization where the candidate will hold the faculty position.

7.2.2. Institutional Commitment (3 pages)

Describe the institutional commitment to the candidate, including total salary, institutional support of salary, endowment or other support, space, and all other agreements between the institution and the candidate. **The institutional commitment must state the total award amount requested.** Provide a brief job description for the candidate should recruitment be successful. This information should be supplied in the form of a letter signed by the applicant institution's president, provost, or appropriate dean.

The letter of institutional commitment must demonstrate the organization's commitment to bringing the candidate to Texas. The following guidelines should be used when outlining the institutional match in the letter. This information may be provided as part of paragraph text or as a tabular summary that states the approximate amounts assigned to each item.

Start-up Package: Complete details including salary and fringe benefits, dedicated personnel, amounts for equipment and supplies, and/or infrastructure that will be offered to the candidate as part of the recruitment award.

Endowment Equivalents: The principal of an endowment may not be included as part of the institutional match, but endowment income over the lifetime of the award may be included.

Rent: Amount for recovery of occupying facility space (ie, "rent") is not a permitted institutional commitment item.

7.2.3. Letter of Support from Department Chair (1 page)

Provide the letter of support from and signed by the chair of the department that the candidate is being recruited to. The following information should be included in the letter:

Recruitment Activities: The letter should provide a description of the recruitment activities, strategies, and priorities that have led to the nomination of this candidate.

Caliber of Candidate: The letter should include a description of the caliber of the candidate and justification of nomination of the candidate by the institution.

Description of Candidate Duties and Certification of 70% Time Commitment to Research.

While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70% of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding. The certification that 70% time will be spent on research must be included.

7.2.4. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the candidate.

7.2.5. Summary of Goals and Objectives

List very broad goals and objectives to be achieved during this award. **This section must be** completed by the candidate.

7.2.6. Research (4 pages)

Summarize the key elements of the candidate's research accomplishments and provide an overview of the proposed research by outlining the background and rationale, hypotheses and aims, strategies, goals, and projected impact of the focus of the research program. Highlight the innovative aspects of this effort and place it into context with regard to what pressing problem in cancer will be addressed. This section of the application must be prepared by the candidate. References cited in this section must be included within the stated page limit. Any appropriate citation format is acceptable; official journal abbreviations should be used.

Candidates for CPRIT Scholar Awards must include the following signed statement at the end of this section. Applications that do not contain this signed statement will be returned without review.

"I understand that I do not need to have made a commitment to *<nominating institution>* before this application has been submitted. However, I also understand that only 1 Texas institution may nominate me for a CPRIT Recruitment Award, and this is the nomination that I have endorsed. Requests to change the recruiting institution during the recruitment process are inappropriate."

7.2.7. Publications

Provide the 5 most significant publications that have resulted from the candidate's research efforts. Publications should be uploaded as PDFs of full-text articles. Only articles that have been published or that have been accepted for publication ("in press") should be submitted.

7.2.8. Timeline (1 page)

Provide a general outline of anticipated major award outcomes to be tracked. Timelines will be reviewed during the evaluation of annual progress reports. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

7.2.9. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the candidate. If the candidate has no current or pending funding, a document stating this must be submitted.

7.2.10. Research Environment (1 page)

Briefly describe the research environment available to support the candidate's research program, including core facilities, training programs, and collaborative opportunities.

7.2.11. Descriptive Biography (Up to 2 pages)

Provide a brief descriptive biography of the candidate, including his or her accomplishments, education and training, professional experience, awards and honors, publications relevant to cancer research, and a brief overview of the candidate's goals if selected to receive the award.

This section of the application must be prepared by the candidate. If the application is approved for funding, this section will be made publicly available on CPRIT's website.

Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or do not meet the eligibility requirements listed above will be administratively withdrawn without review.

8. APPLICATION REVIEW

8.1. Review Process

All eligible applications will be evaluated and scored by the CPRIT Scientific Review Council using the criteria listed in this RFA. Applications may be submitted continuously in response to this RFA, but will generally be reviewed on a monthly basis by the CPRIT Scientific Review Council. Council members may seek additional ad hoc evaluations of candidates. Scientific Review Council members will discuss applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment. Applications approved by Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review, prioritization, and recommendation to the CPRIT Oversight Committee for approval and funding. Approval is based on an application receiving a positive vote from at least two-thirds of the members of the Oversight Committee. The review process is described more fully in CPRIT's Administrative Rules, Chapter 703, Sections 703.6–703.8.

The decision of the Scientific Review Council not to recommend an application is final, and such applications may not be resubmitted for a recruitment award. Notification of review decisions are sent to the nominator.

8.2. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Review Council members, Program Integration Committee members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.9.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals—an Oversight Committee member, a Program Integration Committee member, or a Scientific Review Council member. Applicants should note that the CPRIT Program Integration Committee comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

8.3. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for continued superb performance as a cancer researcher. Also of critical importance is

the strength of the institutional commitment to the candidate. Recruitment efforts are not likely to be successful unless there is a strong commitment from CPRIT and the host institution. It is not necessary that a candidate agree to accept the recruitment offer at the time an application is submitted. However, applicant institutions should have some reasonable expectation that recruitment will be successful if an award is granted by CPRIT.

Review criteria will focus on the overall impression of the candidate, his/her proposed research program, and his/her long-term contribution to and impact on the field of cancer research.

Questions to be considered by the reviewers are as follows:

Quality of the Candidate: Has the candidate made significant, transformative, and sustained contributions to basic, translational, clinical or population-based cancer research? Is the candidate an established and nationally and/or internationally recognized leader in the field? Has the candidate demonstrated excellence in leadership and teaching? Has the candidate provided mentorship, inspiration, and/or professional training opportunities to junior scientists and students? Does the candidate have a strong record of research funding? Does the candidate have a publication history in high-impact journals? Does the candidate show evidence of collaborative interaction with others?

Scientific Merit of Proposed Research: Is the research plan comprehensive and well thought out? Does the proposed research program demonstrate innovation, creativity, and feasibility? Will it expand the boundaries of cancer research beyond traditional methodology by incorporating novel and interdisciplinary techniques? Does the research program integrate with and/or increase collaborative research efforts and relationships at the nominating institution?

Relevance of Candidate's Research: Is the proposed research likely to have a significant impact on reducing the burden of cancer in the near term? Does the research contribute to basic, translational, clinical, or population-based cancer research?

Research Environment: Does the institution have the necessary facilities, expertise, and resources to support the candidate's research program? Is there evidence of strong institutional support? Will the candidate be free of major administrative/clinical responsibilities so that he or she can focus on maintaining and enhancing his or her research program?

9. KEY DATES

RFA

RFA Release

June 22, 2015

Application Receipt and Review Timeline

Application Receipt System opens, 7 AM CT	Application Receipt	Anticipated Application Review	Application Closing Date
June 22, 2015	Continuous	Monthly by the 15 th day of the month	June 20, 2016

10. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Awards made under this RFA are not transferable to another institution. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award.

CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Chapter 701, Section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us.

Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Chapter 703, Sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

11. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Chapter 703, Section 703.11 for specific requirements regarding the demonstration of available funding.

12. CONTACT INFORMATION

12.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via e-mail will be answered within 1 business day. HelpDesk staff members are not in a position to answer questions regarding scientific aspects of applications.

Dates of operation: June 22, 2015, onward (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time

Wednesday, 8 AM to 4 PM central time

Tel: 866-941-7146

E-mail: <u>Help@CPRITGrants.org</u>

12.2. Scientific and Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Senior Program Manager for Research.

Tel: 512-305-8491

E-mail: <u>Help@CPRITGrants.org</u>

Website: www.cprit.state.tx.us

Third Party Observer Reports



CPRIT Recruitment Scientific Review Council Meeting Observation Report

Report #2015-10-19-RES

Program Name: Academic Research

Panel Name: FY16.2 & FY16.3 Recruitment Review

Panel

Panel Date: October 19, 2015 Report Date: October 26, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Recruitment Review Panel peer review of applications for FY16 funding. The meeting was chaired by Richard Kolodner and held via teleconference on October 19, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Recruitment Review Panel meeting held via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Richard Kolodner on October 19, 2015.

The independent observer noted the following during our observation:

- Six applications were discussed within the Recruitment Scientific Review Council Meeting to determine
 which grants would receive CPRIT funding.
- Five peer review panelists, one CPRIT staff member and two SRA employees were present for the meeting.
- One conflict of interest was identified prior to or during the meeting. Applications for one conflict was
 discussed during the peer review panel. The reviewer with the conflict of interest either left the room
 or did not participate telephonically and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Academic Research Recruitment Cycle 16.2 and 16.3 Applications (Academic Research Recruitment Cycle 16.2 and 16.3 Awards Announced at November 19, 2015, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Recruitment Cycle 16.2 and 16.3 include *Recruitment of Established Investigators, Recruitment of Rising Stars*, and *Recruitment of First-Time Tenure-Track Faculty Members* All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted		
Applica	tions considered by the	PIC and Oversight Co	mmittee		
RR160019	Hancock, John	The University of	Prives, Carol		
		Texas Health Science			
		Center at Houston			
Applications Not Recommended for PIC or Oversight Committee Consideration					
None Reported					

De-Identified Overall Evaluation Scores

Recruitment of Established Investigators

Academic Research Recruitment Cycle 16.2 and 16.3

Application ID	Final Overall Evaluation Score
RR160020*	1.0

Final Overall Evaluation Scores and Rank Order Scores





Ludwig Institute for Cancer Research Ltd October 26, 2015

Richard D. Kolodner Ph.D.

Director, San Diego Branch

Head, Laboratory of Cancer Genetics San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

rkolodner@ucsd.edu

San Diego Branch

UC San Diego School of Medicine CMM-East / Rm 3058 9500 Gilman Dr - MC 0669 La Jolla, CA 92093-0669

T 858 534 7804 **F** 858 534 7750

Mr. Pete Geren
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to pgcprit@sidrichardson.org

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Mr. Geren and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit its list of recruitment grant recommendations. The SRC met on Monday, October 19, 2015 to consider the applications submitted to CPRIT under the **Recruitment of Established Investigator, Recruitment of Rising Stars, and Recruitment for First-Time, Tenure Track Faculty Members** Request for Applications for Recruitment Cycles REC 16.2 and 16.3. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. There were no changes to funding amounts, goals, timelines, or project objectives requested by other applicants. The total amount for the applications recommended is \$16,000,000.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, a commitment to cancer research, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.

Sincerely yours,

Richard D. Kolodner, Ph.D.

Chair, CPRIT Scientific Review Council

Attachment



San Diego

ludwigcancerresearch.org

Rank	App ID	Candidate	Organization/Company	Mech.	Budget Requested	Overall Score
1	RR160019	Dung fong Loo	The University of Texas Health Science Center at Houston	RFT	\$2,000,000	1.0
1	KK100019	Dung-fang Lee	at Houston	Kri	\$2,000,000	1.0
2	RR160020	Wei Yang	The University of Texas at Austin	REI	\$6,000,000	1.0
3	RR160022	Andrew D. Rhim	The University of Texas M. D. Anderson Cancer Center	RRS	\$4,000,000	1.8
4	RR160017	Zhijie Liu	The University of Texas Health Science Center at San Antonio	RFT	\$2,000,000	2.5
5	RR160021	Nidhi Sahni	The University of Texas M. D. Anderson Cancer Center	RFT	\$2,000,000	2.5

RFT = Recruitment of First-Time, Tenure-Track Faculty Members

REI = Recruitment of Established Investigators

RRS = Recruitment of Rising Stars



CEO Affidavit Supporting Information

FY 2016—Cycle 2 & 3
Recruitment of First-Time, Tenure-Track
Faculty Members

Request for Applications



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-16-RFT-1

Recruitment of First-Time Tenure-Track Faculty Members

Please also refer to the Instructions for Applicants document, which will be posted on June 22, 2015

Application Receipt Dates:

June 22, 2015-June 20, 2016

FY 2016

Fiscal Year Award Period September 1, 2015-August 31, 2016

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RFA VERSION HISTORY

Rev 6/22/15 RFA release

Rev 9/11/15 Revised Section 5 – Eligibility

• Revised language to indicate that a candidate who has already accepted a position at the recruiting institution prior to the time that the Scientific Review Council recommends the candidate for a recruitment award is not eligible for a recruitment award. Also clarification was added indicating that "if a position is offered to the candidate during the period following the Scientific Review Council's recommendation but prior to the Oversight Committee's final approval, the institution does so at its own risk. There is no guarantee that the recruitment award will be approved by the Oversight Committee."

1. ABOUT CPRIT

The state of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the state of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The principles and priorities of the Scientific Research program will guide CPRIT staff, peer reviewers, and the Scientific Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs. The program priorities for research adopted by the Oversight Committee include funding projects that address:

- A broad range of innovative, investigator-initiated research projects;
- Prevention and early detection;
- Rare and intractable cancers, including childhood cancers;
- Cancers of importance in Texas;
- Computational biology and analytic methods; and
- Infrastructure Development

2. RATIONALE

The aim of this award mechanism is to bolster cancer research in Texas by providing financial support to attract very promising investigators who are pursuing their first faculty appointment at the level of assistant professor (first-time, tenure-track faculty members). These individuals must have demonstrated academic excellence, innovation during predoctoral and/or postdoctoral research training, commitment to pursuing cancer research, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research. Awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research, thereby advancing cancer research efforts and promoting economic development in the state of Texas.

The recruitment of outstanding scientists will greatly enhance programs of scientific excellence in cancer research and will position Texas as a leader in the fight against cancer. Applications may address any research topic related to cancer biology, causation, prevention, detection or screening, or treatment. However, special consideration will be given to candidates with research programs addressing CPRIT's priority areas for research. These include Prevention and Early Detection; Computational Biology and Analytic Methods; Intractable Cancers (brain, lung, liver, pancreas) and Rare Cancers (<15,000 new cases per year), including Childhood, Adolescent and Young Adult Cancers; Population Disparities and Cancers of Particular Importance in Texas (e.g., liver, cervical and lung).

3. RECRUITMENT OBJECTIVES

The goal of this award mechanism is to recruit exceptional faculty to universities and/or cancer research institutions in the state of Texas. All candidates are expected to have completed their doctoral and fellowship training and to have clearly demonstrated truly superior ability as evidenced by their accomplishments during training, proposed research plan, publication record, and letters of recommendation. This CPRIT-supported initiative is designed to enhance innovative programs of excellence by providing research support for promising, early-stage investigators **seeking their first tenure-track position.** CPRIT will provide start-up funding for newly independent investigators, with the goal of augmenting and expanding the institution's efforts in cancer research. Candidates will be expected to develop research projects within the sponsoring institution. Projects should be appropriate for a newly independent investigator and

should foster the development of preliminary data that can be used to prepare applications for future independent research project grants to further both the investigator's research career and the CPRIT mission. The institution will be expected to work with each newly recruited research faculty member to design and execute a faculty career development plan consistent with his or her research emphasis. Relevance to cancer research and to CPRIT's priority areas are important evaluation criteria for CPRIT funding.

Unless prohibited by policy, the institution is also expected to bestow on the newly recruited faculty member the prestigious title of "CPRIT Scholar in Cancer Research," and the faculty member should be strongly encouraged to use this title on letterhead, business cards, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

4. FUNDING INFORMATION

This is a 4-year award and is not renewable, although individuals may apply for other future CPRIT funding as appropriate. Grant funds of up to \$2,000,000 (total costs) for the 4-year period may be requested. Funding is to be used by the candidate to support his or her research program. The award request may include indirect costs of up to 5% of the total award amount (5.263% of the direct costs). CPRIT will make every effort to be flexible in the timing for disbursement of funds; recipients will be asked at the beginning of each year for an estimate of their needs for the year. Funds may not be carried over beyond 4 years. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if very well justified.

Grant funds may not be used for salary support of this candidate or to construct or renovate laboratory space. Consistent with the statutory mandate that the recipient institution demonstrate that it has funds equivalent to one-half of the total grant award amount dedicated to the individual recruited, a total institutional commitment of 50% of the total award will be required. The institutional commitment can be made on a year-by-year basis and may be fulfilled by demonstrating funds dedicated to salary support for the individual recruited as well as expenses for research support, laboratory renovation, and/or relocation to Texas. Grant funding from other sources that the recruited individual may bring with him or her to the institution may also be counted toward the amount necessary for the institutional commitment. No annual limit on the number of potential award recipients has been set.

Note: Depending on the availability of funds, nominations submitted in response to this RFA during the current receipt period may be announced and awarded either in the current fiscal year (prior to August 31) or in the first quarter of the next fiscal year (starting September 1).

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism.
- Candidates must be nominated by the president, provost, vice president for research, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.
- A candidate may be nominated by only 1 institution. If more than 1 institution is interested in a given candidate, negotiations as to which institution will nominate him or her must be concluded before the nomination is made. There is no limit to the number of applications that an institution may submit during a review cycle.
- A candidate who has already accepted a position as assistant professor tenure track at the recruiting institution prior to the time that the Scientific Review Council recommends the candidate for a recruitment award is not eligible for a recruitment award, as an investment by CPRIT is obviously not necessary. No award is final until approved by the Oversight Committee at a public meeting. However, in recognition of the timeline involved with recruiting highly sought-after candidates who are often considering multiple offers, CPRIT's academic research program staff will notify the nominating institution of the Scientific Review Council's recommendation following the Review Council meeting. If a position is offered to the candidate during the period following the Scientific Review Council's recommendation but prior to the Oversight Committee's final approval, the institution does so at its own risk. There is no guarantee that the recruitment award will be approved by the Oversight Committee.
- The candidate must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and reside in Texas for the duration of the appointment. The

- candidate must devote at least 70% time to research activities. Candidates whose major responsibilities are clinical care, teaching, or administration are not eligible.
- At the time of the application, the candidate **must not** hold an appointment at the rank of assistant professor or above (or equivalent) at an accredited academic institution, research institution, industry, government agency, or private foundation not primarily based in Texas. Candidates holding non–tenure-track appointments at the rank of assistant professor are <u>not</u> eligible for this award. Examples of such appointments include Research Assistant Professor, Adjunct Research Assistant Professor, Assistant Professor (Non-Tenure Track), etc. The candidate <u>may or may not</u> reside in Texas at the time the application is submitted and may be nominated for a faculty position at the Texas institution where they are completing postdoctoral training.
- Successful candidates will be offered tenure-track academic positions at the rank of assistant professor.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT. Prior to final approval of an award, the candidate must provide the same certification.
- An applicant is not eligible to receive a CPRIT grant award if the applicant nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member. Prior to final approval of an award, the candidate must provide the same certification.
- The applicant must report whether the applicant institution or organization, the nominator, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not the individuals will receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date

of the grant application. Prior to final approval of an award, the candidate must provide the same certification.

CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in Section 10 and Section 11. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. **RESUBMISSION POLICY**

Resubmissions will not be accepted for the Recruitment of First-Time, Tenure-Track Faculty Members award mechanism. Any nomination for the Recruitment of First-Time, Tenure-Track Faculty Members that was previously submitted to CPRIT and reviewed but was not recommended for funding may not be resubmitted. If a nomination was administratively rejected prior to review, it can be resubmitted in the following cycles.

7. **RESPONDING TO THIS RFA**

7.1. **Application Submission Guidelines**

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be **considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted. Candidates must be nominated by the institution's president, provost, vice president for research, or appropriate dean. The individual submitting the application (nominator) must create a user account in the system to start and submit an application. Furthermore, the Authorized Signing Official (ASO), who is the person authorized to sign and submit the application for the organization, and the Grants Contract/Office of Sponsored Projects Official, who is the individual who will manage the grant contract if an award is made, also must create a user account in CARS.

Applications will be accepted on a continuous basis throughout the remainder of FY16. In order to manage the timely review of nominations, it is anticipated that applications submitted by 11:59 p.m. on the 20th day of each month will be reviewed by the 15th day of the following month. For an application to be considered for review during the monthly cycle, that application must be submitted on or before 11:59 p.m. CPRIT will not extend the submission deadline. During periods when CPRIT does not receive an adequate number of applications, the review may be extended into the following month. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

7.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in <u>Section 5</u> will be administratively withdrawn without review.

7.2.1. Summary of Nomination (2,000 characters)

Provide a brief summary of the nomination. Include the candidate's name, organization from which the candidate is being recruited, and also the department and/or entity within the nominator's organization where the candidate will hold the faculty position.

7.2.2. Institutional Commitment (3 pages)

Describe the institutional commitment to the candidate, including total salary, institutional support of salary, endowment or other support, space, and all other agreements between the institution and the candidate. The institutional commitment must state the total award amount requested. Provide a brief job description for the candidate should recruitment be successful. This information should be supplied in the form of a letter signed by the applicant institution's president, provost, or appropriate dean. The letter of institutional commitment must demonstrate the organization's commitment to bringing the candidate to Texas. The following guidelines should be used when outlining the institutional match in the letter. This information may be provided as part of paragraph text or as a tabular summary that states the approximate amounts assigned to each item.

Start-up Package: Complete details including salary and fringe benefits, dedicated personnel, amounts for equipment and supplies, and/or infrastructure that will be offered to the candidate as part of the recruitment award.

Rent: Amount for recovery of occupying facility space (ie, "rent") is not a permitted institutional commitment item.

7.2.3. Letter of Support from Department Chair (1 page)

Provide the letter of support from and signed by the chair of the department that the candidate is being recruited to. The following information should be included in the letter:

Recruitment Activities: The letter should provide a description of the recruitment activities, strategies, and priorities that have led to the nomination of this candidate.

Caliber of Candidate: The letter should include a description of the caliber of the candidate and justification of the nomination of the candidate by the institution.

Description of Candidate Duties and Certification of 70% Time Commitment to Research.

While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70% of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding. The certification that 70% time will be spent on research must be included.

The letter of support from the department chair <u>must</u> also do the following:

- 1. Describe how the candidate will be independent and autonomous in developing his or her research program at the institution;
- 2. Present a plan for mentoring that includes the design and execution of a faculty career development plan for the candidate.

7.2.4. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the candidate.

7.2.5. Summary of Goals and Objectives

List very broad goals and objectives to be achieved during this award. **This section must be** completed by the candidate.

7.2.6. Research (4 pages)

Summarize the key elements of the candidate's research accomplishments and provide an overview of the proposed research by outlining the background and rationale, hypotheses and aims, strategies, goals, and projected impact of the focus of the research program. Highlight the innovative aspects of this effort and place it into context with regard to what pressing problem in cancer will be addressed. This section of the application must be prepared by the candidate. References cited in this section must be included within the stated page limit. Any appropriate citation format is acceptable; official journal abbreviations should be used.

Candidates for CPRIT Scholar Awards must include the following signed statement at the end of this section. **Applications that do not contain this <u>signed</u> statement will be returned without review.**

"I understand that I do not need to have made a commitment to *<nominating institution>* before this application has been submitted. However, I also understand that only 1 Texas institution may nominate me for a CPRIT Recruitment Award, and this is the nomination that I have endorsed. Requests to change the recruiting institution during the recruitment process are inappropriate."

7.2.7. Publications

Provide the 3 most significant publications that have resulted from the candidate's research efforts. Publications should be uploaded as PDFs of full-text articles. Only articles that have been published or that have been accepted for publication ("in press") should be submitted.

7.2.8. Timeline (1 page)

Provide a general outline of anticipated major award outcomes to be tracked. Timelines will be reviewed during the evaluation of annual progress reports. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

7.2.9. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the candidate. If the candidate has no current or pending funding, a document stating this must be submitted.

7.2.10. Letters of Recommendation

Provide 3 letters of recommendation from individuals who are in a position to detail the candidate's academic and scientific research accomplishments, potential for high-impact research, and ability to make a significant contribution to the field of cancer research.

7.2.11. Research Environment (1 page)

Briefly describe the research environment available to support the candidate's research program, including core facilities, training programs, and collaborative opportunities.

7.2.12. Descriptive Biography (Up to 2 pages)

Provide a brief descriptive biography of the candidate, including his or her accomplishments, education and training, professional experience, awards and honors, publications relevant to cancer research, and a brief overview of the candidate's goals if selected to receive the award. This section of the application must be prepared by the candidate. If the application is approved for funding, this section will be made publicly available on CPRIT's website. Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or do not meet the eligibility requirements listed above will be administratively withdrawn without review.

8. APPLICATION REVIEW

8.1. **Review Process**

All eligible applications will be evaluated and scored by the CPRIT Scientific Review Council using the criteria listed in this RFA. Applications may be submitted continuously in response to this RFA, but will generally be reviewed on a monthly basis by the CPRIT Scientific Review Council. Council members may seek additional ad hoc evaluations of candidates. Scientific Review Council members will discuss applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment. Applications approved by Council will be forwarded to the CPRIT Program Integration

Committee (PIC) for review, prioritization, and recommendation to the CPRIT Oversight Committee for approval and funding. Approval is based on an application receiving a positive vote from at least two-thirds of the members of the Oversight Committee. The review process is described more fully in CPRIT's Administrative Rules, Chapter 703, Sections 703.6–703.8.

The decision of the Scientific Review Council not to recommend an application is final, and such applications may not be resubmitted for a recruitment award. Notification of review decisions are sent to the nominator.

8.1.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Review Council members, Program Integration Committee members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.9.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals—an Oversight Committee member, a Program Integration Committee member, or a Scientific Review Council member. Applicants should note that the CPRIT Program Integration Committee comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional,

serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

8.2. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for continued superb performance as a cancer researcher. Also of critical importance is the strength of the institutional commitment to the candidate. Recruitment efforts are not likely to be successful unless there is a strong commitment from both CPRIT and the host institution.

It is not necessary that a candidate agree to accept the recruitment offer at the time an application is submitted. However, applicant institutions should have some reasonable expectation that recruitment will be successful if an award is granted by CPRIT.

Review criteria will focus on the overall impression of the candidate, his or her proposed research program, and his or her long-term contribution to and impact on the field of cancer research. Questions to be considered by the reviewers are as follows:

Quality of the Candidate: Has the candidate demonstrated academic excellence? Has the candidate received excellent predoctoral and postdoctoral training? Does the candidate show exceptional potential for achieving future impact on basic, translational, clinical, or population-based cancer research in the future? Has the candidate demonstrated a commitment to cancer research? Has the candidate demonstrated independence or the potential for independence?

Scientific Merit of Proposed Research: Is the research plan comprehensive and well thought out? Does the proposed research program demonstrate innovation, creativity, and feasibility? Will it have a significant impact on the field of cancer research? Will the proposed research generate preliminary data that can be used for the preparation of applications for future independent research project grants?

Relevance of Candidate's Research: Is the proposed research likely to have a significant impact on reducing the burden of cancer in the near term? Does the research contribute to basic, translational, clinical, or population-based cancer research?

Letters of Recommendation: Do the letters of recommendation detail the candidate's academic and clinical research accomplishments, potential for high-impact research, and ability to make a significant contribution to the field of cancer research?

Research Environment: Does the institution have the necessary facilities, expertise, and resources to support the candidate's research? Is there evidence of strong institutional support? Will the candidate be free of major administrative/clinical responsibilities so that he or she can focus on growing his or her research? Has the institution identified a mentor who will design and execute a faculty career development plan for the candidate?

9. KEY DATES

RFA

RFA Release

June 22, 2015

Application Receipt and Review Timeline

Application Receipt System opens, 7 AM CT	Application Receipt	Anticipated Application Review	Application Closing Date
June 22, 2015	Continuous	Monthly by the 15 th day of the month	June 20, 2016

10. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Awards made under this RFA are not transferable to another institution. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Chapter 701, Section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us.

Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Chapter 703, Sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

11. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Chapter 703, Section 703.11 for specific requirements regarding the demonstration of available funding.

12. CONTACT INFORMATION

12.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via e-mail will be answered within 1 business day. HelpDesk staff members are not in a position to answer questions regarding scientific aspects of applications.

Dates of operation: June 22, 2015 onward (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 a.m. to 4 p.m. central time

Wednesday, 8 a.m. to 4 p.m. central time

Tel: 866-941-7146

E-mail: <u>Help@CPRITGrants.org</u>

12.2. Scientific and Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Senior Program Manager for Research.

Tel: 512-305-8491

E-mail: Help@CPRITGrants.org

Website: www.cprit.state.tx.us

Third Party Observer Reports



CPRIT Recruitment Scientific Review Council Meeting Observation Report

Report #2015-10-19-RES

Program Name: Academic Research

Panel Name: FY16.2 & FY16.3 Recruitment Review

Panel

Panel Date: October 19, 2015 Report Date: October 26, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Recruitment Review Panel peer review of applications for FY16 funding. The meeting was chaired by Richard Kolodner and held via teleconference on October 19, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Recruitment Review Panel meeting held via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Richard Kolodner on October 19, 2015.

The independent observer noted the following during our observation:

- Six applications were discussed within the Recruitment Scientific Review Council Meeting to determine
 which grants would receive CPRIT funding.
- Five peer review panelists, one CPRIT staff member and two SRA employees were present for the meeting.
- One conflict of interest was identified prior to or during the meeting. Applications for one conflict was
 discussed during the peer review panel. The reviewer with the conflict of interest either left the room
 or did not participate telephonically and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Academic Research Recruitment Cycle 16.2 and 16.3 Applications (Academic Research Recruitment Cycle 16.2 and 16.3 Awards Announced at November 19, 2015, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Recruitment Cycle 16.2 and 16.3 include *Recruitment of Established Investigators, Recruitment of Rising Stars*, and *Recruitment of First-Time Tenure-Track Faculty Members* All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted	
Applications considered by the PIC and Oversight Committee				
RR160019	Hancock, John	The University of	Prives, Carol	
		Texas Health Science		
		Center at Houston		
Applications Not Recommended for PIC or Oversight Committee Consideration				
None Reported				

De-Identified Overall Evaluation Scores

Recruitment of First-Time, Tenure-Track Faculty Members

Academic Research Recruitment Cycle 16.2 and 16.3

Application ID	Final Overall Evaluation Score
RR160019*	1.0
RR160017*	2.5
RR160021*	2.5
aaa	3.0

Final Overall Evaluation Scores and Rank Order Scores





San Diego

Ludwig Institute for Cancer Research Ltd October 26, 2015

Richard D. Kolodner Ph.D.

Director, San Diego Branch

Head, Laboratory of Cancer Genetics San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

rkolodner@ucsd.edu

San Diego Branch

UC San Diego School of Medicine CMM-East / Rm 3058 9500 Gilman Dr - MC 0669 La Jolla, CA 92093-0669

T 858 534 7804 **F** 858 534 7750

Mr. Pete Geren
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to pgcprit@sidrichardson.org

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Mr. Geren and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit its list of recruitment grant recommendations. The SRC met on Monday, October 19, 2015 to consider the applications submitted to CPRIT under the **Recruitment of Established Investigator, Recruitment of Rising Stars, and Recruitment for First-Time, Tenure Track Faculty Members** Request for Applications for Recruitment Cycles REC 16.2 and 16.3. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. There were no changes to funding amounts, goals, timelines, or project objectives requested by other applicants. The total amount for the applications recommended is \$16,000,000.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, a commitment to cancer research, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.

Sincerely yours,

Richard D. Kolodner, Ph.D.

Chair, CPRIT Scientific Review Council

Attachment



San Diego

ludwigcancerresearch.org

Rank	App ID	Candidate	Organization/Company	Mech.	Budget Requested	Overall Score
1	RR160019	Dung fong Loo	The University of Texas Health Science Center at Houston	RFT	\$2,000,000	1.0
1	KK100019	Dung-fang Lee	at Houston	Kri	\$2,000,000	1.0
2	RR160020	Wei Yang	The University of Texas at Austin	REI	\$6,000,000	1.0
3	RR160022	Andrew D. Rhim	The University of Texas M. D. Anderson Cancer Center	RRS	\$4,000,000	1.8
4	RR160017	Zhijie Liu	The University of Texas Health Science Center at San Antonio	RFT	\$2,000,000	2.5
5	RR160021	Nidhi Sahni	The University of Texas M. D. Anderson Cancer Center	RFT	\$2,000,000	2.5

RFT = Recruitment of First-Time, Tenure-Track Faculty Members

REI = Recruitment of Established Investigators

RRS = Recruitment of Rising Stars



CEO Affidavit Supporting Information

FY 2016—Cycle 2 & 3
Recruitment of Rising Stars

Request for Applications



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-16-RRS-1

Recruitment of Rising Stars

Please also refer to the Instructions for Applicants document, which will be posted on June 22, 2015

Application Receipt Dates:

June 22, 2015-June 20, 2016

FY 2016

Fiscal Year Award Period September 1, 2015-August 31, 2016

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RFA VERSION HISTORY

Rev 6/22/15 RFA release

Rev 9/11/15 Revised Section 5 – Eligibility

• Revised language to indicate that a candidate who has already accepted a position at the recruiting institution prior to the time that the Scientific Review Council recommends the candidate for a recruitment award is not eligible for a recruitment award. Also clarification was added indicating that "if a position is offered to the candidate during the period following the Scientific Review Council's recommendation but prior to the Oversight Committee's final approval, the institution does so at its own risk. There is no guarantee that the recruitment award will be approved by the Oversight Committee."

1. ABOUT CPRIT

The state of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to do the following:

- Create and expedite innovation in the area of cancer research and in enhancing the
 potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the state of Texas; and
- Develop and implement the Texas Cancer Plan.

1.1. Research Program Priorities

The Texas Legislature has charged the CPRIT Oversight Committee with establishing program priorities on an annual basis. These priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio. The principles and priorities of the Scientific Research program will guide CPRIT staff, peer reviewers, and the Scientific Review Council on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs. The program priorities for research adopted by the Oversight Committee include funding projects that address:

- A broad range of innovative, investigator-initiated research projects;
- Prevention and early detection;
- Rare and intractable cancers, including childhood cancers;
- Cancers of importance in Texas;
- Computational biology and analytic methods; and
- Infrastructure Development

2. RATIONALE

The aim of this award mechanism is to bolster cancer research in Texas by providing financial support to attract individuals whose work has outstanding merit, who show a marked capacity for self-direction, and who demonstrate the promise for continued and enhanced contributions to the field of cancer research ("Rising Stars"). Awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research, thereby advancing cancer research efforts and promoting economic development in the state of Texas. The recruitment of outstanding scientists will greatly enhance programs of scientific excellence in cancer research and will position Texas as a leader in the fight against cancer. Applications may address any research topic related to cancer biology, causation, prevention, detection or screening, or treatment. However, special consideration will be given to candidates with research programs addressing CPRIT's priority areas for research. These include Prevention and Early Detection; Computational Biology and Analytic Methods; Intractable Cancers (brain, lung, liver, pancreas) and Rare Cancers (<15,000 new cases per year), including Childhood, Adolescent and Young Adult Cancers; Population Disparities and Cancers of Particular Importance in Texas (e.g., liver, cervical and lung).

3. RECRUITMENT OBJECTIVES

The goal of this award mechanism is to recruit exceptional faculty to universities and/or cancer research institutions in the state of Texas. Having already demonstrated extraordinary accomplishments during their initial years of independent research, Rising Stars represent a unique blend of scholastic aptitude, scientific rigor, and commitment to exploring transformational research through the development of creative ideas with high potential.

Candidates who have not historically worked in cancer research but are proposing creative hypotheses and research plans for this field are encouraged to apply. Similarly, candidates pursuing original and potentially high-impact basic science programs that have the potential to be translated toward clinical investigations or provide "proof of principle" are also encouraged to apply. It is expected that the candidate will contribute significantly to and have a major impact on the institution's overall cancer research initiative. Funding will be given for exceptional candidates who will continue to develop new research methods and techniques in the life,

population-based, physical, engineering, or computational sciences and apply them to solving outstanding problems in cancer research that have been inadequately addressed or for which there may be an absence of an established paradigm or technical framework.

Ideal candidates will have specific expertise in cancer-related areas needed to address an institutional priority. Candidates are expected to be approximately at the career level of a late assistant/early associate professor or equivalent. This funding mechanism considers expertise, accomplishments, and breadth of experience vital metrics for guiding CPRIT's investment in that person's originality, insight, and potential for continued contribution. Relevance to cancer research and to CPRIT's priority areas are important evaluation criteria for CPRIT funding.

Unless prohibited by policy, the institution is also expected to bestow on the newly recruited faculty member the prestigious title of "CPRIT Scholar in Cancer Research," and the faculty member should be strongly encouraged to use this title on letterhead, business cards, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

4. FUNDING INFORMATION

This is a 5-year award and is not renewable. Grant funds of up to \$4,000,000 (total costs) over a 5-year period may be requested. Exceptions to this limit will be entertained only if there is compelling written justification. Annual allocations of this award are at the discretion of the awardee, as long as the total award does not exceed \$4,000,000. The award request may include indirect costs of up to 5% of the total award amount (5.263% of the direct costs). CPRIT will make every effort to be flexible in the timing for disbursement of funds; recipients will be asked at the beginning of each year for an estimate of their needs for the year. Funds may not be carried over beyond 5 years. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if very well justified.

Grant funds may be used for salary support of this candidate but may not be used to construct or renovate laboratory space. Consistent with the statutory mandate that the recipient institution demonstrate that it has funds equivalent to one-half of the total grant award amount dedicated to the individual recruited, a total institutional commitment of 50% of the total award will be required. The institutional commitment can be made on a year-by-year basis and may be fulfilled by demonstrating funds dedicated to salary support and endowment for the

individual recruited as well as expenses for research support, laboratory renovation, and/or relocation to Texas. Grant funding from other sources that the recruited individual may bring with him or her to the institution may also be counted toward the amount necessary for the institutional commitment. No annual limit on the number of potential award recipients has been set.

Note: Depending on the availability of funds, nominations submitted in response to this RFA during the current receipt period may be announced and awarded either in the current fiscal year (prior to August 31) or in the first quarter of the next fiscal year (starting September 1).

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism.
- Candidates must be nominated by the president, provost, vice president for research, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.
- A candidate may be nominated by only 1 institution. If more than 1 institution is interested in a given candidate, negotiations as to which institution will nominate him or her must be concluded before the nomination is made. There is no limit to the number of applications that an institution may submit during a review cycle.
- A candidate who has already accepted a position at the recruiting institution prior to the time that the Scientific Review Council recommends the candidate for a recruitment award is <u>not</u> eligible for a recruitment award, as an investment by CPRIT is obviously not necessary. No award is final until approved by the Oversight Committee at a public meeting. However, in recognition of the timeline involved with recruiting highly sought-after candidates who are often considering multiple offers, CPRIT's academic research program staff will notify the nominating institution of the Scientific Review Council's recommendation following the Review Council meeting. If a position is offered to the candidate during the period following the Scientific Review Council's recommendation

- but prior to the Oversight Committee's final approval, the institution does so at its own risk. There is no guarantee that the recruitment award will be approved by the Oversight Committee.
- The candidate must have a doctoral degree, including MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and reside in Texas for the duration of the appointment. The candidate must devote at least 70% time to research activities. Candidates whose major responsibilities are clinical care, teaching, or administration are not eligible.
- At the time of the application, the candidate should hold an appointment at the rank of
 assistant or associate professor tenure-track or tenured (or equivalent) at an accredited
 academic institution, research institution, industry, government agency, or private
 foundation not primarily based in Texas. The candidate <u>must not</u> reside in Texas at the
 time the application is submitted.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT. Prior to final approval of an award, the candidate must provide the same certification.
- An applicant is not eligible to receive a CPRIT grant award if the applicant nominator, any senior member or key personnel listed on the grant application, or any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member. Prior to final approval of an award, the candidate must provide the same certification.
- The applicant must report whether the applicant institution or organization, the nominator, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not the individuals will receive salary or compensation under the grant award, are currently ineligible to receive federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application. Prior to final approval of an award, the candidate must provide the same certification.

CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in Section 10 and Section 11. All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. RESUBMISSION POLICY

Resubmissions will not be accepted for the Recruitment of Rising Stars award mechanism. Any nomination for the Recruitment of Rising Stars that was previously submitted to CPRIT and reviewed but was not recommended for funding may not be resubmitted. If a nomination was administratively rejected prior to review, it can be resubmitted in the following cycles.

7. RESPONDING TO THIS RFA

7.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (https://CPRITGrants.org). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted. Candidates must be nominated by the institution's president, provost, vice president for research, or appropriate dean. The individual submitting the application (nominator) must create a user account in the system to start and submit an application. Furthermore, the Authorized Signing Official (ASO), who is the person authorized to sign and submit the application for the organization, and the Grants Contract/Office of Sponsored Projects Official, who is the individual who will manage the grant contract if an award is made, also must create a user account in CARS.

Applications will be accepted on a continuous basis throughout the remainder of FY16. In order to manage the timely review of nominations, it is anticipated that applications submitted by 11:59 p.m. on the 20th day of each month will be reviewed by the 15th day of the following month. For an application to be considered for review during the monthly cycle, that application

must be submitted on or before 11:59 p.m. CPRIT will not extend the submission deadline. During periods when CPRIT does not receive an adequate number of applications, the review may be extended into the following month. Submission of an application is considered an acceptance of the terms and conditions of the RFA.

7.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens.

Submissions that are missing 1 or more components or do not meet the eligibility requirements listed in <u>Section 5</u> will be administratively withdrawn without review.

7.2.1. Summary of Nomination (2,000 characters)

Provide a brief summary of the nomination. Include the candidate's name, organization from which the candidate is being recruited, and also the department and/or entity within the nominator's organization where the candidate will hold the faculty position.

7.2.2. Institutional Commitment (2 pages)

Describe the institutional commitment to the candidate, including total salary, institutional support of salary, endowment or other support, space, and all other agreements between the institution and the candidate. **The institutional commitment must state the total award amount requested.** Provide a brief job description for the candidate should recruitment be successful. This information should be supplied in the form of a letter signed by the applicant institution's president, provost, or appropriate dean.

The letter of institutional commitment must demonstrate the organization's commitment to bringing the candidate to Texas. The following guidelines should be used when outlining the institutional match in the letter. This information may be provided as part of paragraph text or as a tabular summary that states the approximate amounts assigned to each item.

Start-up Package: Complete details including salary and fringe benefits, dedicated personnel, amounts for equipment and supplies, and/or infrastructure that will be offered to the candidate as part of the recruitment award.

Endowment Equivalents: The principal of an endowment may not be included as part of the institutional match, but endowment income over the lifetime of the award may be included.

Rent: Amount for recovery of occupying facility space (ie, "rent") is not a permitted institutional commitment item.

7.2.3. Letter of Support from Department Chair (1 page)

Provide the letter of support from and signed by the chair of the department that the candidate is being recruited to. The following information should be included in the letter:

Recruitment Activities: The letter should provide a description of the recruitment activities, strategies, and priorities that have led to the nomination of this candidate.

Caliber of Candidate: The letter should include a description of the caliber of the candidate and justification of the nomination of the candidate by the institution.

Description of Candidate Duties and Certification of 70% Time Commitment to Research.

While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70% of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding. The certification that 70% time will be spent on research must be included.

7.2.4. Curriculum Vitae (CV)

Provide a complete CV, and list of publications for the candidate.

7.2.5. Summary of Goals and Objectives

List very broad goals and objectives to be achieved during this award. **This section must be** completed by the candidate.

7.2.6. Research (4 pages)

Summarize the key elements of the candidate's research accomplishments and provide an overview of the proposed research by outlining the background and rationale, hypotheses and aims, strategies, goals, and projected impact of the focus of the research program. Highlight the innovative aspects of this effort, and place it into context with regard to what pressing problem in cancer will be addressed. **This section of the application must be prepared by the candidate.**

References cited in this section must be included within the stated page limit. Any appropriate citation format is acceptable; official journal abbreviations should be used.

Candidates for CPRIT Scholar Awards must include the following signed statement at the end of this section. Applications that do not contain this signed statement will be returned without review. "I understand that I do not need to have made a commitment to *nominating institution* before this application has been submitted. However, I also understand that only 1 Texas institution may nominate me for a CPRIT Recruitment Award, and this is the nomination that I have endorsed. Requests to change the recruiting institution during the recruitment process are inappropriate."

7.2.7. Publications

Provide the 5 most significant publications that have resulted from the candidate's research efforts. Publications should be uploaded as PDFs of full-text articles. Only articles that have been published or that have been accepted for publication ("in press") should be submitted.

7.2.8. Timeline (1 page)

Provide a general outline of anticipated major award outcomes to be tracked. Timelines will be reviewed during the evaluation of annual progress reports. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

7.2.9. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the candidate. If the candidate has no current or pending funding, a document stating this must be submitted.

7.2.10. Research Environment (1 page)

Briefly describe the research environment available to support the candidate's research program, including core facilities and training programs, and collaborative opportunities.

7.2.11. Descriptive Biography (Up to 2 pages)

Provide a brief descriptive biography of the candidate, including his or her accomplishments, education and training, professional experience, awards and honors, publications relevant to

cancer research, and a brief overview of the candidate's goals if selected to receive the award. **This section of the application must be prepared by the candidate.** If the application is approved for funding, this section will be made publicly available on CPRIT's website.

Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing 1 or more of these components, exceed the specified page, word, or budget limits, or do not meet the eligibility requirements listed above will be administratively withdrawn without review.

8. APPLICATION REVIEW

8.1. Review Process

All eligible applications will be evaluated and scored by the CPRIT Scientific Review Council using the criteria listed in this RFA. Applications may be submitted continuously in response to this RFA but will generally be reviewed on a monthly basis by the CPRIT Scientific Review Council. Council members may seek additional ad hoc evaluations of candidates. Scientific Review Council members will discuss applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment. Applications approved by Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review, prioritization, and recommendation to the CPRIT Oversight Committee for approval and funding. Approval is based on an application receiving a positive vote from at least two-thirds of the members of the Oversight Committee. The review process is described more fully in CPRIT's Administrative Rules, Chapter 703, Sections 703.6–703.8.

The decision of the Scientific Review Council not to recommend an application is final, and such applications may not be resubmitted for a recruitment award. Notification of review decisions are sent to the nominator.

8.1.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Review Council members, Program Integration Committee members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign

nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict-of-interest prohibitions. All CPRIT Scientific Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.9.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals—an Oversight Committee member, a Program Integration Committee member, or a Scientific Review Council member. Applicants should note that the CPRIT Program Integration Committee comprises the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

8.2. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for continued superb performance as a cancer researcher. Also of critical importance is the strength of the institutional commitment to the candidate. Recruitment efforts are not likely to be successful unless there is a strong commitment from CPRIT and the host institution. It is not necessary that a candidate agree to accept the recruitment offer at the time an application is submitted. However, applicant institutions should have some reasonable expectation that recruitment will be successful if an award is granted by CPRIT.

Review criteria will focus on the overall impression of the candidate, his/her proposed research program, and his/her long-term contribution to and impact on the field of cancer research.

Questions to be considered by the reviewers are as follows:

Quality of the Candidate: Has the candidate demonstrated extraordinary accomplishments during his or her initial years of independent research? Does the candidate show promise of making important contributions with significant impact to basic, translational, clinical, or population-based cancer research in the future? Has the candidate demonstrated strong self-direction, motivation, and commitment for transformative cancer research?

Scientific Merit of Proposed Research: Is the research plan comprehensive and well thought out? Does the proposed research program demonstrate innovation, creativity, and feasibility? Will it have a significant impact on the field of cancer research? Will it expand the boundaries of cancer research beyond traditional methodology by incorporating novel and interdisciplinary techniques?

Relevance of Candidate's Research: Is the proposed research likely to have a significant impact on reducing the burden of cancer in the near term? Does the research contribute to basic, translational, clinical, or population-based cancer research?

Research Environment: Does the institution have the necessary facilities, expertise, and resources to support the candidate's research? Is there evidence of strong institutional support? Will the candidate be free of major administrative/clinical responsibilities so that he or she can focus on maintaining and enhancing his or her research program? Will the candidate be provided with adequate professional development opportunities to grow as a leader?

9. KEY DATES

RFA

RFA Release

June 22, 2015

Application Receipt and Review Timeline

Application Receipt System opens, 7 AM CT	Application Receipt	Anticipated Application Review	Application Closing Date
June 22, 2015	Continuous	Monthly by the 15 th day of the month	June 20, 2016

10. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Awards made under this RFA are not transferable to another institution. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Chapter 701, Section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Chapter 703, Sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. **Continuation of funding is contingent upon the timely receipt of these reports.** Failure to provide timely and complete reports may waive reimbursement of grant

award costs and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

11. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Chapter 703, Section 703.11 for specific requirements regarding the demonstration of available funding.

12. CONTACT INFORMATION

12.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via e-mail will be answered within 1 business day. HelpDesk staff members are not in a position to answer questions regarding scientific aspects of applications.

Dates of operation: June 22, 2015 onward (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time

Wednesday, 8 AM to 4 PM central time

Tel: 866-941-7146

E-mail: <u>Help@CPRITGrants.org</u>

12.2. Scientific and Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Senior Program Manager for Research.

Tel: 512-305-8491

E-mail: Help@CPRITGrants.org

Website: <u>www.cprit.state.tx.us</u>

Third Party Observer Reports



CPRIT Recruitment Scientific Review Council Meeting Observation Report

Report #2015-10-19-RES

Program Name: Academic Research

Panel Name: FY16.2 & FY16.3 Recruitment Review

Panel

Panel Date: October 19, 2015 Report Date: October 26, 2015

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized an independent party to function as a neutral third-party observer.

Introduction

The subject of this report is the Recruitment Review Panel peer review of applications for FY16 funding. The meeting was chaired by Richard Kolodner and held via teleconference on October 19, 2015.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.



Observation Results Summary

The independent observer participated in the Recruitment Review Panel meeting held via teleconference. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator, and chaired by Richard Kolodner on October 19, 2015.

The independent observer noted the following during our observation:

- Six applications were discussed within the Recruitment Scientific Review Council Meeting to determine
 which grants would receive CPRIT funding.
- Five peer review panelists, one CPRIT staff member and two SRA employees were present for the meeting.
- One conflict of interest was identified prior to or during the meeting. Applications for one conflict was
 discussed during the peer review panel. The reviewer with the conflict of interest either left the room
 or did not participate telephonically and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panelists' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

• An evaluation of the appropriateness or rigor of the review panel's discussion of scientific, technical or programmatic aspects of the applications.

The third party observer was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

Noted Conflicts of Interest

Conflicts of Interest for Academic Research Recruitment Cycle 16.2 and 16.3 Applications (Academic Research Recruitment Cycle 16.2 and 16.3 Awards Announced at November 19, 2015, Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. Applications reviewed in Academic Research Recruitment Cycle 16.2 and 16.3 include *Recruitment of Established Investigators, Recruitment of Rising Stars*, and *Recruitment of First-Time Tenure-Track Faculty Members* All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Application ID	Applicant	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
RR160019	Hancock, John	The University of	Prives, Carol
		Texas Health Science	
		Center at Houston	
Applications Not Recommended for PIC or Oversight Committee Consideration			
None Reported			

De-Identified Overall Evaluation Scores

Recruitment of Rising Stars

Academic Research Recruitment Cycle 16.2 and 16.3

Application ID	Final Overall Evaluation Score
RR160022*	1.8

Final Overall Evaluation Scores and Rank Order Scores





San Diego

Ludwig Institute for Cancer Research Ltd October 26, 2015

Richard D. Kolodner Ph.D.

Director, San Diego Branch

Head, Laboratory of Cancer Genetics San Diego Branch

Distinguished Professor of Cellular & Molecular Medicine, University of California San Diego School of Medicine

rkolodner@ucsd.edu

San Diego Branch

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T 858 534 7804 **F** 858 534 7750

Mr. Pete Geren
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to pgcprit@sidrichardson.org

Mr. Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Mr. Geren and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit its list of recruitment grant recommendations. The SRC met on Monday, October 19, 2015 to consider the applications submitted to CPRIT under the **Recruitment of Established Investigator, Recruitment of Rising Stars, and Recruitment for First-Time, Tenure Track Faculty Members** Request for Applications for Recruitment Cycles REC 16.2 and 16.3. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. There were no changes to funding amounts, goals, timelines, or project objectives requested by other applicants. The total amount for the applications recommended is \$16,000,000.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, a commitment to cancer research, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.

Sincerely yours,

Richard D. Kolodner, Ph.D.

Chair, CPRIT Scientific Review Council

Attachment



San Diego

ludwigcancerresearch.org

Rank	App ID	Candidate	Organization/Company	Mech.	Budget Requested	Overall Score
1	RR160019	Dung fong Loo	The University of Texas Health Science Center at Houston	RFT	\$2,000,000	1.0
1	KK100019	Dung-fang Lee	at Houston	Kri	\$2,000,000	1.0
2	RR160020	Wei Yang	The University of Texas at Austin	REI	\$6,000,000	1.0
3	RR160022	Andrew D. Rhim	The University of Texas M. D. Anderson Cancer Center	RRS	\$4,000,000	1.8
4	RR160017	Zhijie Liu	The University of Texas Health Science Center at San Antonio	RFT	\$2,000,000	2.5
5	RR160021	Nidhi Sahni	The University of Texas M. D. Anderson Cancer Center	RFT	\$2,000,000	2.5

RFT = Recruitment of First-Time, Tenure-Track Faculty Members

REI = Recruitment of Established Investigators

RRS = Recruitment of Rising Stars



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application DP150127 New Company Product Development Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *New Company Product Development Awards* Request for Applications (RFA). CPRIT received 10 applications, for this RFA including 1 that was later withdrawn. This application was assigned to the Product Development Panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas	
County of Travis	
SWORN to and SUBSCRIBED before me, the	
he 5th day of November	, 2015,
by WAYNE R. ROBERTS.	
Sandra Reyes	_
Notary Public, State of Texas	
	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2015 **CYCLE** 4

PROGRAM Product Development

AWARD MECHANISM New Company Product Development Awards (NEWCO)

APPLICATION ID DP150127

APPLICATION TITLE Engineered AXL Decoy Receptor for Treatment of AML &

APPLICATION TITLE
Solid Tumors

APPLICANT NAME Giaccia, Amato
ORGANIZATION Ruga Corporation

PANEL NAME Product Development Panel-1 (PDP-1)

atestry	Compliance Requirement	Information'	Attestation Da
	RFA published in Texas Register	12/05/14	07/09/15
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	01/05/15	07/09/15
	CPRIT Application Receipt System (CARS) closed	02/09/15	07/09/15
	Date application submitted	02/07/15	07/09/15
	Method of submission	CARS	07/09/15
	Within receipt period	YES	07/09/15
7	Appeal to submit application after CARS closed	N/A	07/09/15
	Appeal for late application submission accepted	N/A	07/09/15
	Submission of application fee	YES	10/27/15
	Administrative review notification	N/A	07/09/15
	Donation(s) made to CPRIT/foundation	NO	07/09/15
	Assigned to primary reviewers	03/02/15	07/09/15
. Receipt, Referral,	Applicant notified of review panel assignment	03/11/15	07/09/15
nd Assignment	Primary Reviewer 1 COI signed	02/18/15	07/09/15
na Assignment	Primary (Advocate) Reviewer 2 COI signed	02/18/15	07/09/15
	Primary Reviewer 3 COI signed	02/22/15	07/09/15
	Primary Reviewer 4 COI signed	02/21/15	07/09/15
		03/30/15	07/09/15
	Primary Reviewer 1 critique submitted		07/09/15
	Primary (Advocate) Reviewer 2 critique submitted	03/26/15	07/09/15
	Primary Reviewer 3 critique submitted	03/26/15	07/09/15
	Primary Reviewer 4 critique submitted		
	COI indicated by non-primary reviewer	Pegram, Mark	07/09/15
	COI recused from participation	YES	07/09/15
. Screening	COI indicated by non-primary reviewer	Sarisky, Robert	07/09/15
eleconference	COI recused from participation	YES	07/09/15
/leeting	COI indicated by non-primary reviewer	Saxberg, Bo	07/09/15
	COI recused from participation	YES	07/09/15
	Screening Teleconference Meeting	03/26/15	07/09/15
	Post-Screening Teleconference score report	03/26/15	07/09/15
	Post review statements signed	04/08/15	07/09/15
	Third Party Observer Report	03/30/15	07/10/15
	Recommended for On-Site Meeting	YES	07/09/15
	COI indicated by non-primary reviewer	Pegram, Mark	07/09/15
	COI recused from participation	YES	07/09/15
	COI indicated by non-primary reviewer	Sarisky, Robert	07/09/15
	COI recused from participation	YES	07/09/15
	COI indicated by non-primary reviewer	Saxberg, Bo	07/09/15
. Peer Review	COI recused from participation	YES	07/09/15
/leeting	Peer Review Meeting	04/27/15-04/28/15	07/09/15
	Post review statements signed	04/30/15	07/09/15
	Third Party Observer Report	04/28/15	07/09/15
	Score report delivered to CPDO	05/18/15	07/09/15
	Recommended for due diligence and IP review	YES	07/09/15
	Final due diligence review submitted to PDRC	09/14/15	10/27/15
. Due Diligence and IP	Intellectual Property conflict check	07/15/15	10/28/15
leview	Final intellectual property review submitted	09/19/15	10/28/15
	COI Indicated by PDRC member	NONE	10/14/15
	COI recused from participation	N/A	10/14/15
stant page	Due Diligence Evaluation Meeting / PDRC Meeting	10/12/15	10/14/15
i. Final PDRC tecommendation	Third Party Observer Report	10/20/15	10/27/15
ecommendation		YES	10/14/15
	Recommended for grant award	10/26/15	10/26/15
	PDRC Chair Notification to PIC and OC		
	COI indicated by PIC member	NONE	11/03/15
. PIC Review	COI recused from participation	N/A	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	1
	COI recused from participation	YES/NO or N/A	
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
		YES/NO	1
	Authority to advance funds requested	TES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application PP160010 Evidence-Based Cancer Prevention Services

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Evidence Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received six applications for this RFA. This application was assigned to the 16.1 Prevention Panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

Two applications in response to this RFA with an equal or more favorable score than those recommended were not recommended by the Prevention Review Council (PRC). As

allowed in 25 T.A.C § 703.6(d)(1), the PRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio. The PRC recommendations considered geographical impact, cancer site of the applications as compared to the overall Prevention portfolio, and cost. The letter and rank order list from the PRC Chair explains why some recommended grant applications were ranked ahead of an application with a more favorable score as required by 25 T.A.C. § 703.6(d)(2)(B).

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas		
County of Travis		
CWODN to and CUDSCDIE	BED before me, the undersign	ed authority on
the 5 th day of	November	, 2015,
bv WAYNE R. ROBERTS.		
by WAYNE R. ROBERTS.	0	
by WAYNE R. ROBERTS.		SANDRA J. REYES Notary Public, State of Texas My Commission Expires
by WAYNE R. ROBERTS. Sandra Reves		

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2016 CYCLE 1

PROGRAM Prevention

AWARD MECHANISM Evidence-Based Cancer Prevention Services (EBP)

APPLICATION ID PP160010

APPLICATION TITLE

Maximizing Opportunities for HPV Vaccination in the

Golden Triangle

APPLICANT NAME Berenson, Abbey

ORGANIZATION The University of Texas Medical Branch at Galveston

PANEL NAME 16.1 Prevention Panel - 1 (16.1 PP-1)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/01/15	09/28/15
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	04/30/15	09/28/15
	CPRIT Application Receipt System (CARS) closed	07/09/15	09/28/15
	Date application submitted	07/08/15	09/28/15
	Method of submission	CARS	09/28/15
	Within receipt period	YES	09/28/15
	Appeal to submit application after CARS closed	N/A	09/28/15
	Appeal for late application submission accepted	N/A	09/28/15
	Administrative review notification	N/A	09/28/15
	Donation(s) made to CPRIT/foundation	NO	09/28/15
	Assigned to primary reviewers	08/03/15	09/28/15
2. Receipt, Referral,	Applicant notified of review panel assignment	08/14/15	09/28/15
and Assignment	Primary Reviewer 1 COI signed	07/31/15	09/28/15
	Primary (Advocate) Reviewer 2 COI signed	07/24/15	09/28/15
	Primary Reviewer 3 COI signed	07/27/15	09/28/15
	Primary Reviewer 4 COI signed	07/22/15	09/28/15
	Primary Reviewer 1 critique submitted	09/04/15	09/28/15
	Primary (Advocate) Reviewer 2 critique submitted	08/15/15	09/28/15
	Primary Reviewer 3 critique submitted	08/19/15	09/28/15
	Primary Reviewer 4 critique submitted	09/08/15	09/28/15
	COI indicated by non-primary reviewer	NONE	09/28/15
3. Peer Review	COI recused from participation	N/A	09/28/15
Meeting	Discussed at Peer Review Meeting	YES	09/28/15
_	Peer Review Meeting	09/21/15 - 09/22/15	09/28/15
	Post review statements signed	09/22/15	09/28/15
	Third Party Observer Report	09/30/15	10/14/15
	Score report delivered to CPO	10/01/15	10/13/15
	Recommended for PRC Review	YES	09/28/15
	COI indicated by PRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
4. Final PRC	PRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/29/15	10/29/15
	Recommended for grant award	YES	10/27/15
	PRC Chair Notification to PIC and OC	10/27/15	10/27/15
	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation	M. Kripke, K. Cole	11/03/15
5. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
6. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
- Provide	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	productive to advance runds requested	1123/110	N Comments

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

 $[\]label{eq:mr.cole} \textit{Mr. Cole had a conflict with a different EBP application and did not vote on any EBP applications.}$



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application PP160011 Competitive Continuation/Expansion— Evidence-Based Cancer Prevention Services

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Competitive Continuation/Expansion–Evidence-Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received six applications for this RFA. This application was assigned to the 16.1 Prevention Panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

One application in response to this RFA with an equal or more favorable score than those recommended were not recommended by the Prevention Review Council (PRC). As allowed in 25 T.A.C § 703.6(d)(1), the PRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio. The PRC recommendations considered geographical impact, cancer site of the applications as compared to the overall Prevention portfolio, and cost. The letter and rank order list from the PRC Chair explains why some recommended grant applications were ranked ahead of an application with a more favorable score as required by 25 T.A.C. § 703.6(d)(2)(B).

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R Roberts,

CEO, Cancer Prevention and Research Institute of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2016 CYCLE 1

PROGRAM Prevention

AWARD MECHANISM Competitive Continuation/Expansion–Evidence-Based

Cancer Prevention Services (CCE-EBP)

APPLICATION ID PP160011

APPLICATION TITLE GRACIAS Texas: Genetic Risk Assessment for Cancer in All

South Texas

APPLICANT NAME Tomlinson, Gail

ORGANIZATION The University of Texas Health Science Center at San Antonio

PANEL NAME 16.1 Prevention Panel - 1 (16.1 PP-1)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/01/15	09/28/15
	CPRIT Application Receipt System (CARS) opened	04/30/15	09/28/15
	CPRIT Application Receipt System (CARS) closed	07/09/15	09/28/15
	Date application submitted	07/09/15	09/28/15
1. Pre-Receipt	Method of submission	CARS	09/28/15
	Within receipt period	YES	09/28/15
	Appeal to submit application after CARS closed	N/A	09/28/15
	Appeal for late application submission accepted	N/A	09/28/15
	Administrative review notification	N/A	09/28/15
	Donation(s) made to CPRIT/foundation	NO	09/28/15
	Assigned to primary reviewers	08/03/15	09/28/15
2. Receipt, Referral,	Applicant notified of review panel assignment	08/14/15	09/28/15
and Assignment	Primary Reviewer 1 COI signed	07/31/15	09/28/15
	Primary (Advocate) Reviewer 2 COI signed	07/24/15	09/28/15
	Primary Reviewer 3 COI signed	07/28/15	09/28/15
	Primary Reviewer 4 COI signed	08/03/15	09/28/15
	Primary Reviewer 1 critique submitted	09/04/15	09/28/15
	Primary (Advocate) Reviewer 2 critique submitted	08/15/15	09/28/15
	Primary Reviewer 3 critique submitted	09/04/15	09/28/15
	Primary Reviewer 4 critique submitted	09/07/15	09/28/15
	COI indicated by non-primary reviewer	NONE	09/28/15
3. Peer Review	COI recused from participation	N/A	09/28/15
Meeting	Discussed at Peer Review Meeting	YES	09/28/15
	Peer Review Meeting	09/21/15 - 09/22/15	09/28/15
	Post review statements signed	09/22/15	09/28/15
	Third Party Observer Report	09/30/15	10/14/15
	Score report delivered to CPO	10/01/15	10/13/15
	Recommended for PRC Review	YES	09/28/15
	COI indicated by PRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
4. Final PRC	PRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/29/15	10/29/15
	Recommended for grant award	YES	10/27/15
	PRC Chair Notification to PIC and OC	10/27/15	10/27/15
	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation	N/A	11/03/15
5. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	12,00,10
	COI indicated by Oversight Committee member	NAME or NONE	71
	COI recused from participation	YES/NO or N/A	
6. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	-
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application PP160023 Evidence-Based Cancer Prevention Services – Colorectal Cancer Prevention Coalition

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Evidence-Based Cancer Prevention Services - Colorectal Cancer Prevention Coalition* Request for Applications (RFA). CPRIT received one application for this RFA. This application was assigned to the 16.1 Prevention Panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis
SWORN to and SUBSCRIBED before me, the undersigned authority, on
the <u>5th</u> day of <u>November</u> , 2015, by WAYNE R. ROBERTS.
MATNER. ROBERTS.
Sandra Raves
Notary Public, State of Texas
SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
Notary without Bond

FY

2016

CYCLE

1

PROGRAM

Prevention

AWARD MECHANISM

Evidence-Based Cancer Prevention Services - Colorectal

AWAID MECHANIC

Cancer Prevention Coalition (EBP-CRC)

APPLICATION ID

PP160023

APPLICATION TITLE

Optimizing Colorectal Cancer Screening in East Texas

APPLICANT NAME

Sauter, Edward

ORGANIZATION

The University of Texas Health Center at Tyler

PANEL NAME

16.1 Prevention Panel - 1 (16.1 PP-1)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/01/15	09/28/15
	CPRIT Application Receipt System (CARS) opened	04/30/15	09/28/15
	CPRIT Application Receipt System (CARS) closed	07/09/15	09/28/15
	Date application submitted	07/07/15	09/28/15
L. Pre-Receipt	Method of submission	CARS	09/28/15
	Within receipt period	YES	09/28/15
	Appeal to submit application after CARS closed	N/A	09/28/15
	Appeal for late application submission accepted	N/A	09/28/15
	Administrative review notification	N/A	09/28/15
	Donation(s) made to CPRIT/foundation	NO	09/28/15
	Assigned to primary reviewers	08/03/15	09/28/15
2. Receipt, Referral,	Applicant notified of review panel assignment	08/14/15	09/28/15
and Assignment	Primary Reviewer 1 COI signed	07/22/15	09/28/15
and coordinates	Primary (Advocate) Reviewer 2 COI signed	07/24/15	09/28/15
	Primary (Advocate) Reviewer 2 Col signed	07/22/15	09/28/15
	Primary Reviewer 4 COI signed	07/22/15	09/28/15
	Primary Reviewer 1 critique submitted	09/06/15	09/28/15
	Primary (Advocate) Reviewer 2 critique submitted	08/12/15	09/28/15
	Primary (Advocate) Reviewer 2 Chique submitted	09/08/15	09/28/15
	Primary Reviewer 3 critique submitted Primary Reviewer 4 critique submitted	08/30/15	09/28/15
	COI indicated by non-primary reviewer	Schwartz, Randy	09/28/15
		YES	09/28/15
3. Peer Review Meeting	COI recused from participation	YES	09/28/15
weeting	Discussed at Peer Review Meeting	09/21/15 - 09/22/15	09/28/15
	Peer Review Meeting	09/22/15	09/28/15
	Post review statements signed	09/22/13	10/14/15
	Third Party Observer Report	10/01/15	10/13/15
	Score report delivered to CPO	YES	09/28/15
	Recommended for PRC Review	NONE	10/27/15
	COI indicated by PRC member	N/A	10/27/15
	COI recused from participation		10/27/15
4. Final PRC	PRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/29/15	
	Recommended for grant award	YES	10/27/15
	PRC Chair Notification to PIC and OC	10/27/15	10/27/15
	COI indicated by PIC member	K. Cole	11/03/15
5. PIC Review	COI recused from participation	YES	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	-
	COI indicated by Oversight Committee member	NAME or NONE	1
6. Oversight	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



CEO AFFIDAVIT Application PP160027 Evidence-Based Cancer Prevention Services

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Evidence Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received six applications for this RFA. This application was assigned to the 16.1 Prevention Panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

Two applications in response to this RFA with an equal or more favorable score than those recommended were not recommended by the Prevention Review Council (PRC). As

allowed in 25 T.A.C § 703.6(d)(1), the PRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio. The PRC recommendations considered geographical impact, cancer site of the applications as compared to the overall Prevention portfolio, and cost. The letter and rank order list from the PRC Chair explains why some recommended grant applications were ranked ahead of an application with a more favorable score as required by 25 T.A.C. § 703.6(d)(2)(B).

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the uncerthe day of November by WAYNE R. ROBERTS.	dersigned authority, on, 2015,
SA A	SANDRA J. REYES Notary Public, State of Toxas My Commission Expires
Sandra Reyes V Notary Public, State of Texas	My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

FY 2016 **CYCLE** 1

PROGRAM Prevention

AWARD MECHANISM Evidence-Based Cancer Prevention Services (EBP)
APPLICATION ID PP160027

APPLICATION TITLE Improving Service Delivery to Cancer Survivors in Primary

Care Settings

APPLICANT NAME Foxhall, Lewis

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME 16.1 Prevention Panel - 1 (16.1 PP-1)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/01/15	09/28/15
	CPRIT Application Receipt System (CARS) opened	04/30/15	09/28/15
	CPRIT Application Receipt System (CARS) closed	07/09/15	09/28/15
4 Day Daysint	Date application submitted	07/09/15	09/28/15
1. Pre-Receipt	Method of submission	CARS	09/28/15
	Within receipt period	YES	09/28/15
	Appeal to submit application after CARS closed	N/A	09/28/15
	Appeal for late application submission accepted	N/A	09/28/15
	Administrative review notification	07/23/15	09/28/15
	Donation(s) made to CPRIT/foundation	NO	09/28/15
	Assigned to primary reviewers	08/03/15	09/28/15
2. Receipt, Referral,	Applicant notified of review panel assignment	08/14/15	09/28/15
and Assignment	Primary Reviewer 1 COI signed	08/03/15	09/28/15
	Primary (Advocate) Reviewer 2 COI signed	07/25/15	09/28/15
	Primary Reviewer 3 COI signed	07/22/15	09/28/15
	Primary Reviewer 4 COI signed	07/22/15	09/28/15
	Primary Reviewer 1 critique submitted	08/31/15	09/28/15
	Primary (Advocate) Reviewer 2 critique submitted	08/28/15	09/28/15
	Primary Reviewer 3 critique submitted	09/08/15	09/28/15
	Primary Reviewer 4 critique submitted	08/20/15	09/28/15
	COI indicated by non-primary reviewer	Vanderpool, Robin	09/28/15
3. Peer Review	COI recused from participation	YES	09/28/15
Meeting	Discussed at Peer Review Meeting	YES	09/28/15
	Peer Review Meeting	09/21/15 - 09/22/15	09/28/15
	Post review statements signed	09/22/15	09/28/15
	Third Party Observer Report	09/30/15	10/14/15
	Score report delivered to CPO	10/01/15	10/13/15
	Recommended for PRC Review	YES	09/28/15
	COI indicated by PRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
4. Final PRC	PRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/29/15	10/29/15
	Recommended for grant award	YES	10/27/15
	PRC Chair Notification to PIC and OC	10/27/15	10/27/15
	COI indicated by PIC member	K. Cole	11/03/15
	COI recused from participation	YES & M. Kripke	11/03/15
5. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
6. Oversight Committee Approval	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
		123/110	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

The identity of the attesting party is retained by CPRIT.



CEO AFFIDAVIT Application PP160032 Cancer Prevention Promotion and Navigation to Clinical Services

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Cancer Prevention Promotion and Navigation to Clinical Services* Request for Applications (RFA). CPRIT received five applications for this RFA, including two that were later withdrawn. This application was assigned to the 16.1 Prevention Panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis
SWORN to and SUBSCRIBED before me, the undersigned authority, on the
Sandra Reves
Notary Public, State of Texas SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
Notary without Bond

FY 2016

CYCLE 1

PROGRAM Prevention

AWARD MECHANISM Cancer Prevention Promotion and Navigation to Clinical Services (PN)

APPLICATION ID PP160032

Family Health History-based Colorectal Cancer Prevention

APPLICATION TITLE and Navigation to Clinical Services among Uninsured

Chinese Americans in Texas

APPLICANT NAME
Chen, Lei-Shih

ORGANIZATION Texas A&M University

PANEL NAME 16.1 Prevention Panel - 1 (16.1 PP-1)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/01/15	09/28/15
	CPRIT Application Receipt System (CARS) opened	04/30/15	09/28/15
	CPRIT Application Receipt System (CARS) closed	07/09/15	09/28/15
	Date application submitted	07/09/15	09/28/15
L. Pre-Receipt	Method of submission	CARS	09/28/15
	Within receipt period	YES	09/28/15
	Appeal to submit application after CARS closed	N/A	09/28/15
	Appeal for late application submission accepted	N/A	09/28/15
	Administrative review notification	N/A	09/28/15
	Donation(s) made to CPRIT/foundation	NO	09/28/15
	Assigned to primary reviewers	08/03/15	09/28/15
2. Receipt, Referral,	Applicant notified of review panel assignment	08/14/15	09/28/15
and Assignment	Primary Reviewer 1 COI signed	07/22/15	09/28/15
and Masignificate	Primary (Advocate) Reviewer 2 COI signed	07/24/15	09/28/15
	Primary (Advocate) Reviewer 2 Corsigned Primary Reviewer 3 COI signed	07/22/15	09/28/15
	Primary Reviewer 4 COI signed	07/22/15	09/28/15
	Primary Reviewer 1 critique submitted	08/30/15	09/28/15
	Primary (Advocate) Reviewer 2 critique submitted	08/15/15	09/28/15
	Primary (Advocate) Reviewer 2 Chique submitted	09/09/15	09/28/15
	Primary Reviewer 3 Critique submitted	09/08/15	09/28/15
		NONE	09/28/15
	COI indicated by non-primary reviewer	N/A	09/28/15
3. Peer Review	COI recused from participation	YES	09/28/15
Meeting	Discussed at Peer Review Meeting	09/21/15 - 09/22/15	09/28/15
	Peer Review Meeting	09/22/15	09/28/15
	Post review statements signed	09/30/15	10/14/15
	Third Party Observer Report		10/13/15
	Score report delivered to CPO	10/01/15	09/28/15
	Recommended for PRC Review	YES	10/27/15
	COI indicated by PRC member	NONE	
	COI recused from participation	N/A	10/27/15
4. Final PRC	PRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/29/15	10/29/15
	Recommended for grant award	YES	10/27/15
	PRC Chair Notification to PIC and OC	10/27/15	10/27/15
	COI indicated by PIC member	NONE	11/03/15
5. PIC Review	COI recused from participation	N/A	11/03/15
3. FIC REVIEW	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
6. Oversight	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	1
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



CEO AFFIDAVIT Application PP160036

Competitive Continuation/Expansion— Evidence-Based Cancer Prevention Services

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Competitive Continuation/Expansion–Evidence-Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received six applications for this RFA. This application was assigned to the 16.1 Prevention Panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
 - One application in response to this RFA with an equal or more favorable score than those recommended were not recommended by the Prevention Review Council (PRC). As

allowed in 25 T.A.C § 703.6(d)(1), the PRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio. The PRC recommendations considered geographical impact, cancer site of the applications as compared to the overall Prevention portfolio, and cost. The letter and rank order list from the PRC Chair explains why some recommended grant applications were ranked ahead of an application with a more favorable score as required by 25 T.A.C. § 703.6(d)(2)(B).

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 5 day of November , 2015, by WAYNE R. ROBERTS.

Sandra Reyes
Notary Public, State of Texas

Notary Public, State of Texas

SEPTEMBER 30, 2017

Notary without Bond

FY 2016 **CYCLE** 1

PROGRAM Prevention

AWARD MECHANISM Competitive Continuation/Expansion—Evidence-Based

Cancer Prevention Services (CCE-EBP)

APPLICATION ID PP160036

Establishing a Comprehensive Cancer Prevention and APPLICATION TITLE Support Program within Asian American Communities in

Houston and Austin Areas of Texas

APPLICANT NAME Sun, Helen

ORGANIZATION Light and Salt Association

PANEL NAME 16.1 Prevention Panel - 1 (16.1 PP-1)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/01/15	09/28/15
	CPRIT Application Receipt System (CARS) opened	04/30/15	09/28/15
	CPRIT Application Receipt System (CARS) closed	07/09/15	09/28/15
1. Pre-Receipt	Date application submitted	07/09/15	09/28/15
1. Fre-Neceipt	Method of submission	CARS	09/28/15
	Within receipt period	YES	09/28/15
	Appeal to submit application after CARS closed	N/A	09/28/15
	Appeal for late application submission accepted	N/A	09/28/15
	Administrative review notification	N/A	09/28/15
	Donation(s) made to CPRIT/foundation	NO	09/28/15
	Assigned to primary reviewers	08/03/15	09/28/15
2. Receipt, Referral,	Applicant notified of review panel assignment	08/14/15	09/28/15
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	Primary Reviewer 3 critique submitted	09/08/15	09/28/15
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3. Peer Review	COI recused from participation	N/A	09/28/15
Meeting	Discussed at Peer Review Meeting	YES	09/28/15
Micering		09/21/15 - 09/22/15	09/28/15
	Peer Review Meeting		
	Post review statements signed Third Porty Observer Panert	09/22/15	09/28/15
	Third Party Observer Report	09/30/15	10/14/15
	Score report delivered to CPO	10/01/15	10/13/15
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Recommendation	Third Party Observer Report	10/29/15	10/29/15
	Recommended for grant award	YES	10/27/15
	PRC Chair Notification to PIC and OC	10/27/15	10/27/15
	COI indicated by PIC member	NONE	11/03/15
5. PIC Review	COI recused from participation	N/A	11/03/15
J. TR. REVIEW	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
6. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	4
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CEO AFFIDAVIT Application PP160042 Evidence-Based Cancer Prevention Services

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

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CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

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- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

Two applications in response to this RFA with an equal or more favorable score than those recommended were not recommended by the Prevention Review Council (PRC). As

allowed in 25 T.A.C § 703.6(d)(1), the PRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio. The PRC recommendations considered geographical impact, cancer site of the applications as compared to the overall Prevention portfolio, and cost. The letter and rank order list from the PRC Chair explains why some recommended grant applications were ranked ahead of an application with a more favorable score as required by 25 T.A.C. § 703.6(d)(2)(B).

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the the	undersigned authority, on, 2015,
by WAYNE R. ROBERTS.	SANDRA J. REYES Notary Public, State of Texas
Sandra Reyes Notary Public, State of Texas	My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

FY 2016 **CYCLE** 1

APPLICANT NAME

PROGRAM Prevention

AWARD MECHANISM Evidence-Based Cancer Prevention Services (EBP)

APPLICATION ID PP160042

APPLICATION TITLE

Using Best Practices to Promote HPV Vaccination in Rural

Primary Care Settings Parra-Medina, Deborah

ORGANIZATION The University of Texas Health Science Center at San

Antonio

PANEL NAME 16.1 Prevention Panel - 1 (16.1 PP-1)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/01/15	09/28/15
	CPRIT Application Receipt System (CARS) opened	04/30/15	09/28/15
	CPRIT Application Receipt System (CARS) closed	07/09/15	09/28/15
	Date application submitted	07/09/15	09/28/15
1. Pre-Receipt	Method of submission	CARS	09/28/15
	Within receipt period	YES	09/28/15
	Appeal to submit application after CARS closed	N/A	09/28/15
	Appeal for late application submission accepted	N/A	09/28/15
	Administrative review notification	N/A	09/28/15
	Donation(s) made to CPRIT/foundation	NO	09/28/15
	Assigned to primary reviewers	08/03/15	09/28/15
2. Receipt, Referral,	Applicant notified of review panel assignment	08/14/15	09/28/15
and Assignment	Primary Reviewer 1 COI signed	07/22/15	09/28/15
	Primary (Advocate) Reviewer 2 COI signed	07/25/15	09/28/15
	Primary Reviewer 3 COI signed	07/28/15	09/28/15
	Primary Reviewer 4 COI signed	07/31/15	09/28/15
	Primary Reviewer 1 critique submitted	09/08/15	09/28/15
	Primary (Advocate) Reviewer 2 critique submitted	08/30/15	09/28/15
	Primary Reviewer 3 critique submitted	09/04/15	09/28/15
	Primary Reviewer 4 critique submitted	09/08/15	09/28/15
	COI indicated by non-primary reviewer	Vanderpool, Robin	09/28/15
3. Peer Review	COI recused from participation	YES	09/28/15
Meeting	Discussed at Peer Review Meeting	YES	09/28/15
	Peer Review Meeting	09/21/15 - 09/22/15	09/28/15
	Post review statements signed	09/22/15	09/28/15
	Third Party Observer Report	09/30/15	10/14/15
	Score report delivered to CPO	10/01/15	10/13/15
	Recommended for PRC Review	YES	09/28/15
	COI indicated by PRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
4. Final PRC	PRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/29/15	10/29/15
	Recommended for grant award	YES	10/27/15
	PRC Chair Notification to PIC and OC	10/27/15	10/27/15
	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation	M. Kripke, K. Cole	11/03/15
5. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

Mr. Cole had a conflict with a different EBP application and did not vote on any EBP applications.



CEO AFFIDAVIT Application PP160047 Competitive Continuation/Expansion— Evidence-Based Cancer Prevention Services

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Competitive Continuation/Expansion–Evidence-Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received six applications for this RFA. This application was assigned to the 16.1 Prevention Panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

One application in response to this RFA with an equal or more favorable score than those recommended were not recommended by the Prevention Review Council (PRC). As allowed in 25 T.A.C \S 703.6(d)(1), the PRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio. The PRC recommendations considered geographical impact, cancer site of the applications as compared to the overall Prevention portfolio, and cost. The letter and rank order list from the PRC Chair explains why some recommended grant applications were ranked ahead of an application with a more favorable score as required by 25 T.A.C. \S 703.6(d)(2)(B).

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 5th day of November, 2015, by WAYNE R. ROBERTS.

Sandra Reyes
Notary Public State of Texas

 FY
 2016

 CYCLE
 1

PROGRAM Prevention

AWARD MECHANISM

Competitive Continuation/Expansion-Evidence-Based Cancer

Prevention Services (CCE-EBP)

APPLICATION ID PP160047

A Community Based Program to Increase Breast and Cervical

APPLICATION TITLE Cancer Screening and HPV Vaccination to Reduce the Impact of

Breast and Certical Cancer Among Latinas

APPLICANT NAME Savas, Lara

ORGANIZATION The University of Texas Health Science Center at Houston

PANEL NAME 16.1 Prevention Panel - 1 (16.1 PP-1)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	05/01/15	09/28/15
	CPRIT Application Receipt System (CARS) opened	04/30/15	09/28/15
	CPRIT Application Receipt System (CARS) closed	07/09/15	09/28/15
1. Pre-Receipt	Date application submitted	07/09/15	09/28/15
1. Fre-Neceipt	Method of submission	CARS	09/28/15
	Within receipt period	YES	09/28/15
	Appeal to submit application after CARS closed	N/A	09/28/15
	Appeal for late application submission accepted	N/A	09/28/15
	Administrative review notification	N/A	09/28/15
	Donation(s) made to CPRIT/foundation	NO	09/28/15
	Assigned to primary reviewers	08/03/15	09/28/15
2. Receipt, Referral,	Applicant notified of review panel assignment	08/14/15	09/28/15
and Assignment	Primary Reviewer 1 COI signed	07/27/15	09/28/15
	Primary (Advocate) Reviewer 2 COI signed	07/25/15	09/28/15
	Primary Reviewer 3 COI signed	07/24/15	09/28/15
	Primary Reviewer 4 COI signed	07/22/15	09/28/15
	Primary Reviewer 1 critique submitted	09/08/15	09/28/15
	Primary (Advocate) Reviewer 2 critique submitted	08/20/15	09/28/15
	Primary Reviewer 3 critique submitted	09/08/15	09/28/15
	Primary Reviewer 4 critique submitted	08/19/15	09/28/15
	COI indicated by non-primary reviewer	Brownson, Ross	09/28/15
3. Peer Review	COI recused from participation	YES	09/28/15
Meeting	Discussed at Peer Review Meeting	YES	09/28/15
	Peer Review Meeting	09/21/15 - 09/22/15	09/28/15
	Post review statements signed	09/22/15	09/28/15
	Third Party Observer Report	09/30/15	10/14/15
	Score report delivered to CPO	10/01/15	10/13/15
	Recommended for PRC Review	YES	09/28/15
	COI indicated by PRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
4. Final PRC	PRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/29/15	10/29/15
N.C.C.	Recommended for grant award	YES YES	10/27/15
	PRC Chair Notification to PIC and OC	10/27/15	10/27/15
	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation		
5. PIC Review	PIC review meeting	N/A 11/03/15	11/03/15
	Recommended for grant award		11/03/15
		YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
6. Oversight	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CEO AFFIDAVIT Application PP160048 Dissemination of CPRIT-Funded Cancer Prevention and Control Interventions

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Dissemination of CPRIT-Funded Cancer Prevention and Control Interventions* Request for Applications (RFA). CPRIT received two applications for this RFA. This application was assigned to the 16.1 Prevention Panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the day of November by WAYNE R. ROBERTS.	he undersigned authority, on, 2015,
Sandra Reyes	
Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas
	My Commission Expires SEPTEMBER 30, 2017 Notary without Bond

FY 2016 **CYCLE** 1

PROGRAM Prevention

AWARD MECHANISM
Dissemination of CPRIT-Funded Cancer Prevention and

Control Interventions (DI)

APPLICATION ID PP160048

APPLICATION TITLE Training CHWs for More Effective Cancer Education and

Navigation

APPLICANT NAME Bolin, Jane

ORGANIZATION Texas A&M University System Health Science Center

PANEL NAME 16.1 Prevention Panel - 1 (16.1 PP-1)

Category	Compliance Requirement	Information	Attestation Dat
	RFA published in Texas Register	05/01/15	09/28/15
	CPRIT Application Receipt System (CARS) opened	04/30/15	09/28/15
	CPRIT Application Receipt System (CARS) closed	07/09/15	09/28/15
	Date application submitted	07/09/15	09/28/15
L. Pre-Receipt	Method of submission	CARS	09/28/15
	Within receipt period	YES	09/28/15
	Appeal to submit application after CARS closed	N/A	09/28/15
	Appeal for late application submission accepted	N/A	09/28/15
	Administrative review notification	N/A	09/28/15
	Donation(s) made to CPRIT/foundation	NO	09/28/15
	Assigned to primary reviewers	08/03/15	09/28/15
2. Receipt, Referral,	Applicant notified of review panel assignment	08/14/15	09/28/15
and Assignment	Primary Reviewer 1 COI signed	07/28/15	09/28/15
ŭ	Primary (Advocate) Reviewer 2 COI signed	07/24/15	09/28/15
	Primary Reviewer 3 COI signed	08/03/15	09/28/15
	Primary Reviewer 4 COI signed	07/22/15	09/28/15
	Primary Reviewer 1 critique submitted	09/07/15	09/28/15
	Primary (Advocate) Reviewer 2 critique submitted	08/30/15	09/28/15
	Primary Reviewer 3 critique submitted	09/07/15	09/28/15
	Primary Reviewer 4 critique submitted	08/18/15	09/28/15
	COI indicated by non-primary reviewer	Escobedo, Luis	09/28/15
3. Peer Review	COI recused from participation	YES	09/28/15
Meeting	Discussed at Peer Review Meeting	YES	09/28/15
	Peer Review Meeting	09/21/15 - 09/22/15	09/28/15
	Post review statements signed	09/22/15	09/28/15
	Third Party Observer Report	09/30/15	10/14/15
	Score report delivered to CPO	10/01/15	10/13/15
	Recommended for PRC Review	YES	09/28/15
	COI indicated by PRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
4. Final PRC	PRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/29/15	10/29/15
il Commendation	Recommended for grant award	YES	10/27/15
	PRC Chair Notification to PIC and OC	10/27/15	10/27/15
	COI indicated by PIC member	K. Cole	11/03/15
	COI recused from participation	YES	11/03/15
5. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
		DATE	12,00,10
	CEO Notification to Oversight Committee COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
6. Oversight		YES/NO	
	Donation(s) made to CPRIT/foundation Presented to CPRIT Oversight Committee	11/18/15	
Committee Approval	Award approved by Oversight Committee	YES/NO	-
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



CEO AFFIDAVIT Application PP160049 Competitive Continuation/Expansion— Evidence-Based Cancer Prevention Services

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Competitive Continuation/Expansion–Evidence-Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received six applications for this RFA. This application was assigned to the 16.1 Prevention Panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

One application in response to this RFA with an equal or more favorable score than those recommended were not recommended by the Prevention Review Council (PRC). As allowed in 25 T.A.C \S 703.6(d)(1), the PRC's numerical rank order is substantially based on the final overall evaluation score, but also takes into consideration how well the grant application achieves program priorities and the overall program portfolio. The PRC recommendations considered geographical impact, cancer site of the applications as compared to the overall Prevention portfolio, and cost. The letter and rank order list from the PRC Chair explains why some recommended grant applications were ranked ahead of an application with a more favorable score as required by 25 T.A.C. \S 703.6(d)(2)(B).

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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an n

May 2 N	
Wayne R. Roberts,	
CEO, Cancer Prevention and Research Institu	ate of Texas
State of Texas	
County of Travis	
County of Travis	
SWORN to and SUBSCRIBED before me, the	ne undersigned authority on
the 5 th day of November	. 2015,
	, 2013,
by WAYNE R. ROBERTS.	
Λ	The state of the s
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	SANDRA J. REYES Notary Public, State of Texas
	My Commission Expires
Sandra Reyes	SEPTEMBER 30, 2017
Notary Public, State of Texas	Notary without Bond

2016 FY CYCLE 1

PROGRAM Prevention

Competitive Continuation/Expansion-Evidence-Based AWARD MECHANISM

Cancer Prevention Services (CCE-EBP)

APPLICATION ID PP160049

Expansion of a Comprehensive Cervical Cancer Screening

Program for Medically Underserved Women in Harris APPLICATION TITLE

County

APPLICANT NAME Anderson, Matthew ORGANIZATION Baylor College of Medicine

16.1 Prevention Panel - 1 (16.1 PP-1) PANEL NAME

Category	Compliance Requirement	Information	Attestation Dat
	RFA published in Texas Register	05/01/15	09/28/15
	CPRIT Application Receipt System (CARS) opened	04/30/15	09/28/15
	CPRIT Application Receipt System (CARS) closed	07/09/15	09/28/15
	Date application submitted	07/09/15	09/28/15
1. Pre-Receipt	Method of submission	CARS	09/28/15
	Within receipt period	YES	09/28/15
	Appeal to submit application after CARS closed	N/A	09/28/15
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	Administrative review notification	N/A	09/28/15
	Donation(s) made to CPRIT/foundation	NO	09/28/15
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2. Receipt, Referral,	Applicant notified of review panel assignment	08/14/15	09/28/15
and Assignment	Primary Reviewer 1 COI signed	07/27/15	09/28/15
and Assignment	Primary (Advocate) Reviewer 2 COI signed	07/25/15	09/28/15
		07/31/15	09/28/15
	Primary Reviewer 3 COI signed	07/24/15	09/28/15
	Primary Reviewer 4 COI signed		
	Primary Reviewer 1 critique submitted	09/08/15	09/28/15
	Primary (Advocate) Reviewer 2 critique submitted	08/20/15	09/28/15
	Primary Reviewer 3 critique submitted	09/07/15	09/28/15
	Primary Reviewer 4 critique submitted	09/08/15	09/28/15
	COI indicated by non-primary reviewer	NONE	09/28/15
3. Peer Review	COI recused from participation	N/A	09/28/15
Meeting	Discussed at Peer Review Meeting	YES	09/28/15
	Peer Review Meeting	09/21/15 - 09/22/15	09/28/15
	Post review statements signed	09/22/15	09/28/15
	Third Party Observer Report	09/30/15	10/14/15
	Score report delivered to CPO	10/01/15	10/13/15
	Recommended for PRC Review	YES	09/28/15
-	COI indicated by PRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
4. Final PRC	PRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/29/15	10/29/15
	Recommended for grant award	YES	10/27/15
	PRC Chair Notification to PIC and OC	10/27/15	10/27/15
	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation	N/A	11/03/15
5. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	1
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
5 O	Donation(s) made to CPRIT/foundation	YES/NO	
6. Oversight		11/18/15	
Committee Approval	Presented to CPRIT Oversight Committee		
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	



CEO AFFIDAVIT Application PP160051 Dissemination of CPRIT-Funded Cancer Prevention and Control Interventions

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Dissemination of CPRIT-Funded Cancer Prevention and Control Interventions* Request for Applications (RFA). CPRIT received two applications for this RFA. This application was assigned to the 16.1 Prevention Panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R/Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the day of November by WAYNE R. ROBERTS.	
Sandra Reves	
Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

FY 2016 **CYCLE** 1

PROGRAM Prevention

AWARD MECHANISM Dissemination of CPRIT-Funded Cancer Prevention and Control Interventions (DI)

APPLICATION ID PP160051

APPLICATION TITLE Dissemination of an Evidence-Based HPV Vaccination Intervention in Community and Clinical Settings

APPLICANT NAME Fernandez, Maria

ORGANIZATION The University of Texas Health Science Center at Houston

PANEL NAME 16.1 Prevention Panel - 1 (16.1 PP-1)

Category	Compliance Requirement	Information	Attestation Dat
	RFA published in Texas Register	05/01/15	09/28/15
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	04/30/15	09/28/15
	CPRIT Application Receipt System (CARS) closed	07/09/15	09/28/15
	Date application submitted	07/09/15	09/28/15
	Method of submission	CARS	09/28/15
	Within receipt period	YES	09/28/15
	Appeal to submit application after CARS closed	N/A	09/28/15
	Appeal for late application submission accepted	N/A	09/28/15
	Administrative review notification	N/A	09/28/15
	Donation(s) made to CPRIT/foundation	NO	09/28/15
	Assigned to primary reviewers	08/03/15	09/28/15
2. Receipt, Referral,	Applicant notified of review panel assignment	08/14/15	09/28/15
and Assignment	Primary Reviewer 1 COI signed	07/28/15	09/28/15
•	Primary (Advocate) Reviewer 2 COI signed	07/24/15	09/28/15
	Primary Reviewer 3 COI signed	07/31/15	09/28/15
	Primary Reviewer 4 COI signed	07/27/15	09/28/15
	Primary Reviewer 1 critique submitted	09/08/15	09/28/15
	Primary (Advocate) Reviewer 2 critique submitted	09/01/15	09/28/15
	Primary Reviewer 3 critique submitted	09/08/15	09/28/15
	Primary Reviewer 4 critique submitted	09/08/15	09/28/15
	COI indicated by non-primary reviewer	NONE	09/28/15
3. Peer Review	COI recused from participation	N/A	09/28/15
Meeting	Discussed at Peer Review Meeting	YES	09/28/15
Wiccellig	Peer Review Meeting	09/21/15 - 09/22/15	09/28/15
	Post review statements signed	09/22/15	09/28/15
	Third Party Observer Report	09/30/15	10/14/15
	Score report delivered to CPO	10/01/15	10/13/15
	Recommended for PRC Review	YES	09/28/15
		NONE	10/27/15
	COI indicated by PRC member	N/A	10/27/15
	COI recused from participation	10/23/15	10/27/15
4. Final PRC	PRC Meeting	10/29/15	10/27/15
Recommendation	Third Party Observer Report	YES YES	10/23/13
	Recommended for grant award		10/27/15
	PRC Chair Notification to PIC and OC	10/27/15	
	COI indicated by PIC member	K. Cole	11/03/15
5. PIC Review	COI recused from participation	YES	-
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
6. Oversight Committee Approval	COI indicated by Oversight Committee member	NAME OF NONE	-
	COI recused from participation	YES/NO or N/A	-
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	-
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



CEO AFFIDAVIT Application PP160056 Cancer Prevention Promotion and Navigation to Clinical Services

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Cancer Prevention Promotion and Navigation to Clinical Services* Request for Applications (RFA). CPRIT received five applications for this RFA, including two that were later withdrawn. This application was assigned to the 16.1 Prevention Panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Røberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis			
SWORN to and SUBSCRIBED before me, the undersigned authority, on the			
Sandra Reyes Notary Public, State of Texas			
SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017 Notary without Bond			
The state of the s			

FY 2016 CYCLE 1

PROGRAM Prevention

AWARD MECHANISM Cancer Prevention Promotion and Navigation to Clinical

APPLICATION ID Services (PN)
PP160056

APPLICATION TITLE REACH Rural Education and Awareness for Community

Health

APPLICANT NAME Hoelscher, Bill

ORGANIZATION Coastal Bend Wellness Foundation
PANEL NAME 16.1 Prevention Panel - 1 (16.1 PP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/01/15	09/28/15
	CPRIT Application Receipt System (CARS) opened	04/30/15	09/28/15
	CPRIT Application Receipt System (CARS) closed	07/09/15	09/28/15
	Date application submitted	07/09/15	09/28/15
	Method of submission	CARS	09/28/15
	Within receipt period	YES	09/28/15
	Appeal to submit application after CARS closed	N/A	09/28/15
	Appeal for late application submission accepted	N/A	09/28/15
	Administrative review notification	N/A	09/28/15
	Donation(s) made to CPRIT/foundation	NO	09/28/15
	Assigned to primary reviewers	08/03/15	09/28/15
2. Receipt, Referral,	Applicant notified of review panel assignment	08/14/15	09/28/15
and Assignment	Primary Reviewer 1 COI signed	07/24/15	09/28/15
	Primary (Advocate) Reviewer 2 COI signed	07/25/15	09/28/15
	Primary Reviewer 3 COI signed	07/22/15	09/28/15
	Primary Reviewer 4 COI signed	07/28/15	09/28/15
	Primary Reviewer 1 critique submitted	09/08/15	09/28/15
	Primary (Advocate) Reviewer 2 critique submitted	09/07/15	09/28/15
	Primary Reviewer 3 critique submitted	09/08/15	09/28/15
	Primary Reviewer 4 critique submitted	09/08/15	09/28/15
	COI indicated by non-primary reviewer	NONE	09/28/15
3. Peer Review	COI recused from participation	N/A	09/28/15
Meeting	Discussed at Peer Review Meeting	YES	09/28/15
	Peer Review Meeting	09/21/15 - 09/22/15	09/28/15
	Post review statements signed	09/22/15	09/28/15
	Third Party Observer Report	09/30/15	10/14/15
	Score report delivered to CPO	10/01/15	10/13/15
	Recommended for PRC Review	YES	09/28/15
	COI indicated by PRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
l. Final PRC	PRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/29/15	10/29/15
	Recommended for grant award	YES	10/27/15
	PRC Chair Notification to PIC and OC	10/27/15	10/27/15
	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation	N/A	11/03/15
. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	11/03/13
	COI indicated by Oversight Committee member	NAME OF NONE	
5. Oversight Committee Approval	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO OTIV/A	
	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



CEO AFFIDAVIT Application RR160017 Recruitment of First-Time, Tenure-Track Faulty Members Nomination of Dr. Zhijie Liu

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time*, *Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received four applications for this RFA. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 5th day of November , 2015, by WAYNE R. ROBERTS.

Sandra Reyes
Notary Public, State of Texas

SANDRA J. REYES
Notary Public, State of Texas
My Commission Expires
SEPTEMBER 30, 2017
Notary without Bond

FY 2016 **CYCLE** 2

PROGRAM Research

AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)

APPLICATION ID RR16001

APPLICATION TITLE Recruitment of First-Time, Tenure Track for Dr. Zhijie (Jason) Liu

NOMINATOR NAME Dr. Francisco Gonzalez-Scarano

CANDIDATE NAME Dr. Zhijie Liu

ORGANIZATION The University of Texas Health Science Center at San Antonio

PANEL NAME Recruitment FY16 Cycle 2 and 3 (REC_16.2-3)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA Approved by CSO	09/18/15	10/20/15
	RFA published in Texas Register	09/11/15	10/20/15
	CPRIT Application Receipt Cycle opened	07/21/15	10/20/15
	CPRIT Application Receipt Cycle closed	08/20/15	10/20/15
	Date application submitted	08/18/15	10/20/15
	Method of submission	CARS	10/20/15
	Within receipt period	YES	10/20/15
	Administrative review notification	N/A	10/20/15
	Donation(s) made to CPRIT/foundation	NO	10/20/15
2. Receipt, Referral,	Assigned to primary reviewers	10/02/15	10/20/15
and Assignment	Applicant notified of review panel assignment	N/A	10/20/15
ŭ	Primary Reviewer 1 COI signed	09/28/15	10/20/15
	Primary Reviewer 2 COI signed	09/23/15	10/20/15
	Primary Reviewer 1 critique submitted	10/19/15	10/20/15
	Primary Reviewer 2 critique submitted	10/16/15	10/20/15
	COI indicated by non-primary reviewer	NONE	10/20/15
	COI recused from participation	N/A	10/20/15
3. Peer Review	Discussed at Peer Review Meeting	YES	10/20/15
Meeting	Peer Review Meeting	10/19/15	10/20/15
	Post review statements signed	10/20/15	10/21/15
	Third Party Observer Report	10/26/15	10/27/15
	Score report delivered to CSO	10/22/15	10/21/15
	Recommended for SRC Review	YES	10/20/15
	COI indicated by SRC member	NONE	10/20/15
	COI recused from participation	N/A	10/20/15
4. Final SRC	SRC Meeting	10/19/15	10/20/15
Recommendation	Third Party Observer Report	10/26/15	10/27/15
recommendation	Recommended for grant award	YES	10/20/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
		YES	11/04/15
	Applicant not employed by grantee prior to SRC date	NONE	11/04/15
F DIC Davieno	COI indicated by PIC member	M. Kripke*	11/04/15
5. PIC Review	COI recused from participation	11/03/15	11/04/15
	PIC review meeting	YES YES	11/04/15
	Recommended for grant award	DATE	11/04/13
	CEO Notification to Oversight Committee	NAME or NONE	_
6. Oversight	COI indicated by Oversight Committee member		
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	

^{*} Dr. Kripke has an approved conflict of interest waiver on file for FY 2016 regarding MD Anderson.

The identity of the attesting party is retained by CPRIT.



CEO AFFIDAVIT Application RR160019 Recruitment of First-Time, Tenure-Track Faulty Members Nomination of Dr. Dung-fang Lee

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time*, *Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received four applications for this RFA. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on

the 5th day of November

, 2015,

by WAYNE R. ROBERTS.

Sandra Reyes

Notary Public, State of Texas

SANDRA J. REYES
Notary Public, State of Texas
My Commission Expires
SEPTEMBER 30, 2017

Notary without Bond

 FY
 2016

 CYCLE
 3

 PROGRAM
 Research

AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)

APPLICATION ID RR160019

APPLICATION TITLE Recruitment of Dr Dung-fang Lee

NOMINATOR NAME Dr. John F Hancock
CANDIDATE NAME Dr. Dung-fang Lee

ORGANIZATION The University of Texas Health Science Center at Houston

PANEL NAME Recruitment FY16 Cycle 2 and 3 (REC_16.2-3)

Category	Compliance Requirement	Information	Attestation Date
	RFA Approved by CSO	09/18/15	10/20/15
	RFA published in Texas Register	09/11/15	10/20/15
	CPRIT Application Receipt Cycle opened	08/21/15	10/20/15
1. Pre-Receipt	CPRIT Application Receipt Cycle closed	09/20/15	10/20/15
	Date application submitted	09/17/15	10/20/15
	Method of submission	CARS	10/20/15
	Within receipt period	YES	10/20/15
	Administrative review notification	N/A	10/20/15
	Donation(s) made to CPRIT/foundation	NO	10/20/15
2. Receipt, Referral,	Assigned to primary reviewers	10/02/15	10/20/15
and Assignment	Applicant notified of review panel assignment	N/A	10/20/15
•	Primary Reviewer 1 COI signed	09/23/15	10/20/15
	Primary Reviewer 2 COI signed	09/23/15	10/20/15
	Primary Reviewer 1 critique submitted	10/19/15	10/20/15
	Primary Reviewer 2 critique submitted	10/16/15	10/20/15
	COI indicated by non-primary reviewer	Prives, Carol	10/20/15
	COI recused from participation	YES	10/20/15
3. Peer Review	Discussed at Peer Review Meeting	YES	10/20/15
Meeting	Peer Review Meeting	10/19/15	10/20/15
· ·	Post review statements signed	10/20/15	10/21/15
	Third Party Observer Report	10/26/15	10/27/15
	Score report delivered to CSO	10/22/15	10/21/15
	Recommended for SRC Review	YES	10/20/15
	COI indicated by SRC member	Prives, Carol	10/20/15
	COI recused from participation	YES	10/20/15
4. Final SRC	SRC Meeting	10/19/15	10/20/15
Recommendation	Third Party Observer Report	10/26/15	10/27/15
	Recommended for grant award	YES	10/20/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	Applicant not employed by grantee prior to SRC date	YES	11/04/15
	COI indicated by PIC member	M. Kripke*	11/04/15
5. PIC Review	COI recused from participation	N/A	11/04/15
	PIC review meeting	11/03/15	11/04/15
	Recommended for grant award	YES	11/04/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
6. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

^{*} Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding M.D. Anderson.

The identity of the attesting party is retained by CPRIT.



CEO AFFIDAVIT Application RR160020 Recruitment of Established Investigators Nomination of Dr. Wei Yang

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Established Investigators* Request for Applications (RFA). CPRIT received one application for this RFA. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the day of November_by WAYNE R. ROBERTS.	he undersigned authority, on, 2015,
Sandra Reyes Notary Public, State of Texas	SANDRA J. REYES
	Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 3

 PROGRAM
 Research

AWARD MECHANISM Recruitment of Established Investigators (REI)

APPLICATION ID RR160020

APPLICATION TITLE

Mechanistic Investigation of DNA Repair Pathways and Implications

for Cancer

NOMINATOR NAME Dr. Shelley Payne

CANDIDATE NAME Dr. Wei Yang

ORGANIZATION The University of Texas at Austin

PANEL NAME Recruitment FY16 Cycle 2 and 3 (REC_16.2-3)

Category	Compliance Requirement	Information	Attestation Date
	RFA Approved by CSO	09/18/15	10/20/15
	RFA published in Texas Register	09/11/15	10/20/15
	CPRIT Application Receipt Cycle opened	08/21/15	10/20/15
1. Pre-Receipt	CPRIT Application Receipt Cycle closed	09/20/15	10/20/15
191	Date application submitted	09/20/15	10/20/15
	Method of submission	CARS	10/20/15
	Within receipt period	YES	10/20/15
	Administrative review notification	N/A	10/20/15
	Donation(s) made to CPRIT/foundation	NO	10/20/15
2. Receipt, Referral,	Assigned to primary reviewers	10/02/15	10/20/15
and Assignment	Applicant notified of review panel assignment	N/A	10/20/15
	Primary Reviewer 1 COI signed	09/28/15	10/20/15
	Primary Reviewer 2 COI signed	09/28/15	10/20/15
	Primary Reviewer 1 critique submitted	10/18/15	10/20/15
	Primary Reviewer 2 critique submitted	10/19/15	10/20/15
	COI indicated by non-primary reviewer	NONE	10/20/15
	COI recused from participation	N/A	10/20/15
3. Peer Review	Discussed at Peer Review Meeting	YES	10/20/15
Meeting	Peer Review Meeting	10/19/15	10/20/15
	Post review statements signed	10/20/15	10/21/15
	Third Party Observer Report	10/26/15	10/27/15
	Score report delivered to CSO	10/22/15	10/21/15
	Recommended for SRC Review	YES	10/20/15
	COI indicated by SRC member	NONE	10/20/15
	COI recused from participation	N/A	10/20/15
4. Final SRC	SRC Meeting	10/19/15	10/20/15
Recommendation	Third Party Observer Report	10/26/15	10/27/15
	Recommended for grant award	YES	10/20/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	Applicant not employed by grantee prior to SRC date	YES	11/04/15
	COI indicated by PIC member	NONE	11/04/15
5. PIC Review	COI recused from participation	N/A	11/04/15
	PIC review meeting	11/03/15	11/04/15
	Recommended for grant award	YES	11/04/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
6. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT.



CEO AFFIDAVIT Application RR160021 Recruitment of First-Time, Tenure-Track Faulty Members Nomination of Dr. Nidhi Sahni

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time*, *Tenure-Track Faculty Members* Request for Applications (RFA). CPRIT received four applications for this RFA. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas	
County of Travis	
SWORN to and SUBSCRIBED before me, the	ne undersioned authority, on
the 5th day of November	, 2015,
by WAYNE R. ROBERTS.	
Sandra Reves	_
Notary Public, State of Texas	
	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2016
CYCLE 3
PROGRAM Research

AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)

APPLICATION ID RR160021

APPLICATION TITLE Recruitment of First-time, Tenure-Track Faculty - Dr. Nidhi Sahni

NOMINATOR NAME Dr. Ethan Dmitrovsky
CANDIDATE NAME Dr. Nidhi Sahni

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Recruitment FY16 Cycle 2 and 3 (REC_16.2-3)

Sategory	Compliance Requirement	Information	Attestation Dat
	RFA Approved by CSO	09/18/15	10/20/15
	RFA published in Texas Register	09/11/15	10/20/15
	CPRIT Application Receipt Cycle opened	08/21/15	10/20/15
L. Pre-Receipt	CPRIT Application Receipt Cycle closed	09/20/15	10/20/15
	Date application submitted	09/18/15	10/20/15
	Method of submission	CARS	10/20/15
	Within receipt period	YES	10/20/15
	Administrative review notification	N/A	10/20/15
	Donation(s) made to CPRIT/foundation	NO	10/20/15
2. Receipt, Referral,	Assigned to primary reviewers	10/02/15	10/20/15
and Assignment	Applicant notified of review panel assignment	N/A	10/20/15
and the British	Primary Reviewer 1 COI signed	09/23/15	10/20/15
	Primary Reviewer 2 COI signed	09/28/15	10/20/15
	Primary Reviewer 1 critique submitted	10/16/15	10/20/15
	Primary Reviewer 2 critique submitted	10/19/15	10/20/15
	COI indicated by non-primary reviewer	NONE	10/20/15
	COI recused from participation	N/A	10/20/15
3. Peer Review	Discussed at Peer Review Meeting	YES	10/20/15
Meeting	Peer Review Meeting	10/19/15	10/20/15
Meering	Post review statements signed	10/20/15	10/21/15
	Third Party Observer Report	10/26/15	10/27/15
	Score report delivered to CSO	10/22/15	10/21/15
	Recommended for SRC Review	YES	10/20/15
	COI indicated by SRC member	NONE	10/20/15
	COI recused from participation	N/A	10/20/15
	SRC Meeting	10/19/15	10/20/15
4. Final SRC Recommendation	Third Party Observer Report	10/26/15	10/27/15
Recommendation		YES	10/20/15
	Recommended for grant award	10/26/15	10/28/15
	SRC Chair Notification to PIC and OC	YES	11/05/15
	Applicant not employed by grantee prior to SRC date	NONE	11/05/15
	COI indicated by PIC member	M. Kripke*	11/05/15
5. PIC Review	COI recused from participation	11/03/15	11/05/15
	PIC review meeting	YES	11/05/15
	Recommended for grant award	DATE	11/03/13
	CEO Notification to Oversight Committee		
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
6. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

^{*} Dr. Kripke has an approved conflict of interest waiver on file for FY 2016 rearding MD Anderson.

The identity of the attesting party is retained by CPRIT.



CEO AFFIDAVIT Application RR160022 Recruitment of Rising Stars Nomination of Dr. Andrew D. Rhim

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Rising Stars* Request for Applications (RFA). CPRIT received one application for this RFA. This application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

2016

CYCLE

3

PROGRAM

Research

AWARD MECHANISM Recruitment of Rising Stars (RRS)

APPLICATION ID

RR160022

APPLICATION TITLE

Recruitment of Rising Star - Dr. Andrew D. Rhim

NOMINATOR NAME Dr. Ethan Dmitrovsky

CANDIDATE NAME

Dr. Andrew Rhim

ORGANIZATION

The University of Texas M. D. Anderson Cancer Center

PANEL NAME

Recruitment FY16 Cycle 2 and 3 (REC_16.2-3)

Entegory	Compliance Requirement	Information	Attestation Date
	RFA Approved by CSO	09/18/15	10/20/15
	RFA published in Texas Register	09/11/15	10/20/15
	CPRIT Application Receipt Cycle opened	08/21/15	10/20/15
1. Pre-Receipt	CPRIT Application Receipt Cycle closed	09/20/15	10/20/15
·	Date application submitted	09/18/15	10/20/15
	Method of submission	CARS	10/20/15
	Within receipt period	YES	10/20/15
	Administrative review notification	N/A	10/20/15
	Donation(s) made to CPRIT/foundation	NO	10/20/15
2. Receipt, Referral,	Assigned to primary reviewers	10/02/15	10/20/15
and Assignment	Applicant notified of review panel assignment	N/A	10/20/15
•	Primary Reviewer 1 COI signed	09/30/15	10/20/15
	Primary Reviewer 2 COI signed	09/28/15	10/20/15
	Primary Reviewer 1 critique submitted	10/18/15	10/20/15
	Primary Reviewer 2 critique submitted	10/18/15	10/20/15
	COI indicated by non-primary reviewer	NONE	10/20/15
	COI recused from participation	N/A	10/20/15
3. Peer Review	Discussed at Peer Review Meeting	YES	10/20/15
Meeting	Peer Review Meeting	10/19/15	10/20/15
	Post review statements signed	10/20/15	10/21/15
	Third Party Observer Report	10/26/15	10/27/15
	Score report delivered to CSO	10/22/15	10/21/15
	Recommended for SRC Review	YES	10/20/15
	COI indicated by SRC member	NONE	10/20/15
	COI recused from participation	N/A	10/20/15
4. Final SRC	SRC Meeting	10/19/15	10/20/15
Recommendation	Third Party Observer Report	10/26/15	10/27/15
	Recommended for grant award	YES	10/20/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	Applicant not employed by grantee prior to SRC date	YES	11/05/15
	COI indicated by PIC member	NONE	11/05/15
5. PIC Review	COI recused from participation	M. Kripke*	11/05/15
J. FIC REVIEW	PIC review meeting	11/03/15	11/05/15
	Recommended for grant award	YES	11/05/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
6. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	DATE	
committee Approval	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	_

^{*} Dr. Kripke has an approved conflict of interest waiver on file for FY 2016 rearding MD Anderson.

The identity of the attesting party is retained by CPRIT.



CEO AFFIDAVIT Application RP160013 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Clinical and Translational Cancer Research and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 5th day of Novembey, 2015, by WAYNE R. ROBERTS.

Sandra Reves
Notary Public, State of Texas

SANDRA J. REVES
Notary Public, State of Texas
My Commission Expires
SEPTEMBER 30, 2017
Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2016 CYCLE 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160013

APPLICATION TITLE Visualizing T-cell Trafficking

APPLICANT NAME Kundra, Vikas

ORGANIZATION The University of Texas M., D. Anderson Cancer Center

PANEL NAME 16,1 Clinical / Translational Cancer Research (16.1 C/TCR)

Category	Compliance Requirement	Intermetion	Attestation Dat
	RFA published in Texas Register	02/27/15	09/29/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	09/29/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	09/29/15
	Date application submitted	05/13/15	09/29/15
1. Pre-Receipt	Method of submission	CARS	09/29/15
	Within receipt period	YES	09/29/15
	Appeal to submit application after CARS closed	N/A	09/29/15
	Appeal for late application submission accepted	N/A	09/29/15
	Administrative review notification	N/A	09/29/15
	Donation(s) made to CPRIT/foundation	NO	09/29/15
	Assigned to primary reviewers	07/23/15	09/29/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	09/29/15
and Assignment	Primary Reviewer 1 COI signed	06/25/15	09/29/15
	Primary Reviewer 2 COI signed	06/25/15	09/29/15
	Primary Reviewer 3 COI signed	06/23/15	09/29/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	09/29/15
	Primary Reviewer 1 critique submitted	08/13/15	09/29/15
	Primary Reviewer 2 critique submitted	07/24/15	09/29/15
	Primary Reviewer 2 critique submitted	08/11/15	09/29/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	09/29/15
3. Preliminary	COI indicated by non-primary reviewer	Engelhard, Victor	09/29/15
Evaluation	COI indicated by non-primary reviewer	Riddell, Stanley	09/29/15
	Preliminary Evaluation score summary sent to Chair	08/17/15	09/29/15
	Recommended for full review	YES	09/29/15
	Applicant notified of outcome	09/01/15	09/29/15
		08/25/15	09/29/15
	Assigned to primary reviewers	06/25/15	09/29/15
	Primary Reviewer 1 COI signed	06/25/15	09/29/15
	Primary Reviewer 2 COI signed	06/23/15	09/29/15
	Primary Reviewer 3 COI signed Primary (Advocate) Reviewer 4 COI signed	08/27/15	09/29/15
		09/20/15	09/29/15
	Primary Reviewer 1 critique submitted	09/02/15	09/29/15
	Primary Reviewer 2 critique submitted	09/28/15	09/29/15
	Primary Reviewer 3 critique submitted	09/06/15	09/29/15
4. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	Engelhard, Victor	10/13/15
Meeting	COI indicated by non-primary reviewer	YES YES	10/13/15
	COI recused from participation	Riddell, Stanley	10/13/15
	COI indicated by non-primary reviewer	YES YES	10/13/15
	COI recused from participation	YES	10/15/15
	Discussed at Peer Review Meeting	09/29/15	10/06/15
	Peer Review Meeting		10/13/15
	Post review statements signed	10/12/15	10/13/15
	Third Party Observer Report		10/23/15
	Score report delivered to CSO	10/19/15	
	Recommended for SRC Review	YES	10/13/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
6. PIC Review	COI recused from participation	M. Kripke	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CEO AFFIDAVIT Application RP160015 Research Training Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Research Training Awards* Request for Applications (RFA). CPRIT received 13 applications for this RFA. This application was assigned to the Cancer Prevention Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Røberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on

November

the __5th_ day of ____

, 2015,

by WAYNE R. ROBERTS.

Sandra Reyes

Notary Public, State of Texas

SANDRA J. REYES

Notary Public, State of Texas

My Commission Expires

SEPTEMBER 30, 2017

Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY CYCLE 2016

PROGRAM

Research

AWARD MECHANISM Research Training Awards (RTA)

APPLICATION ID

RP160015

APPLICATION TITLE

Collaborative Training of a New Cadre of Innovative Cancer

Prevention Researchers

APPLICANT NAME

Ness, Roberta

ORGANIZATION

The University of Texas Health Science Center at Houston

PANEL NAME

16.1 Cancer Prevention Research (16,1 CPR)

Category	Compliance Requirement	Information	Attestation Dat
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
1 Due Deseint	Date application submitted	05/19/15	10/09/15
1. Pre-Receipt	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	N/A	10/09/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
and Assignment	Primary Reviewer 1 COI signed	N/A	10/09/15
	Primary Reviewer 2 COI signed	N/A	10/09/15
	Primary Reviewer 3 COI signed	N/A	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	N/A	10/09/15
	Primary Reviewer 2 critique submitted	N/A	10/09/15
	Primary Reviewer 3 critique submitted	N/A	10/09/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
Evaluation	COI indicated by non-primary reviewer	N/A	10/09/15
	Preliminary Evaluation score summary sent to Chair	N/A	10/09/15
	Recommended for full review	N/A	10/09/15
	Applicant notified of outcome	N/A	10/09/15
	Assigned to primary reviewers	07/16/15	10/09/15
	Primary Reviewer 1 COI signed	06/25/15	10/09/15
	Primary Reviewer 2 COI signed	06/22/15	10/09/15
	Primary Reviewer 3 COI signed	07/09/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	06/18/15	10/09/15
	Primary Reviewer 1 critique submitted	08/23/15	10/09/15
	Primary Reviewer 2 critique submitted	09/14/15	10/09/15
	Primary Reviewer 3 critique submitted	08/19/15	10/09/15
4. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	09/09/15	10/09/15
4. Peer Keview Meeting	COI indicated by non-primary reviewer	Haiman, Christopher	10/09/15
wieeting	COI recused from participation	YES	10/09/15
	COI indicated by non-primary reviewer	Kushi, Lawrence	10/09/15
	COI recused from participation	YES	10/09/15
	Discussed at Peer Review Meeting	YES	10/09/15
	Peer Review Meeting	09/30/15	10/09/15
	Post review statements signed	10/05/15	10/22/15
	Third Party Observer Report	10/07/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/09/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
5. PIC Review	COI recused from participation	N/A	11/03/15
or remember	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



CEO AFFIDAVIT Application RP160019 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Clinical and Translational Cancer Research and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas	
County of Travis	
CINCODAL A LOUDGODIDED 1 Comments	densioned outbouits, on
SWORN to and SUBSCRIBED before me, the	-
the 5th day of November	, 2015,
by WAYNE R. ROBERTS.	
Λ	
	_
Sandra Reyes	
Notary Public, State of Texas	
	SANDRA J. REYES
	Notary Public, State of Texas
	Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	and the second of the second o
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160019

An Adaptive Personalized Clinical Trial using a Patient-APPLICATION TITLE Derived Xenograft Strategy to Overcome Ibrutinib

Resistance in Mantle Cell Lymphoma

APPLICANT NAME Wang, Michael

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME 16.1 Clinical / Translational Cancer Research (16.1 C/TCR)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	02/27/15	09/29/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	09/29/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	09/29/15
	Date application submitted	05/15/15	09/29/15
L. Pre-Receipt	Method of submission	CARS	09/29/15
	Within receipt period	YES	09/29/15
	Appeal to submit application after CARS closed	N/A	09/29/15
	Appeal for late application submission accepted	N/A	09/29/15
	Administrative review notification	N/A	09/29/15
	Donation(s) made to CPRIT/foundation	NO	09/29/15
	Assigned to primary reviewers	07/23/15	09/29/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	09/29/15
and Assignment	Primary Reviewer 1 COI signed	06/30/15	09/29/15
	Primary Reviewer 2 COI signed	06/19/15	09/29/15
	Primary Reviewer 3 COI signed	06/25/15	09/29/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	09/29/15
	Primary Reviewer 1 critique submitted	08/11/15	09/29/15
	Primary Reviewer 2 critique submitted	08/10/15	09/29/15
	Primary Reviewer 3 critique submitted	08/13/15	09/29/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	09/29/15
Evaluation	COI indicated by non-primary reviewer	NONE	09/29/15
cvaluation	Preliminary Evaluation score summary sent to Chair	08/17/15	09/29/15
	Recommended for full review	YES	09/29/15
		09/01/15	09/29/15
	Applicant notified of outcome	08/25/15	09/29/15
	Assigned to primary reviewers	06/30/15	09/29/15
	Primary Reviewer 1 COI signed	06/19/15	09/29/15
	Primary Reviewer 2 COI signed	06/25/15	09/29/15
	Primary Reviewer 3 COI signed		09/29/15
	Primary (Advocate) Reviewer 4 COI signed	06/15/15	09/29/15
	Primary Reviewer 1 critique submitted	09/21/15	
	Primary Reviewer 2 critique submitted	09/13/15	09/29/15
4. Peer Review	Primary Reviewer 3 critique submitted	09/23/15	09/29/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	08/29/15	09/29/15
	COI indicated by non-primary reviewer	NONE	10/13/15
	COI recused from participation	N/A	10/13/15
	Discussed at Peer Review Meeting	YES	10/06/15
	Peer Review Meeting	09/29/15	10/06/15
	Post review statements signed	10/12/15	10/13/15
	Third Party Observer Report	10/07/15	10/14/15
	Score report delivered to CSO	10/19/15	10/23/15
	Recommended for SRC Review	YES	10/13/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	5RC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
e euc p-ul-uu	COI recused from participation	M. Kripke	11/03/15
5. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CEO AFFIDAVIT Application RP160022 Individual Investigator Research Awards for Cancer in Children and Adolescents

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 45 applications for this RFA, including 1 that was later withdrawn. This application was assigned to the Clinical and Translational Cancer Research and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas	
County of Travis	
SWORN to and SUBSCRIBED before me the day of Novembey by WAYNE R. ROBERTS.	, the undersigned authority, on, 2015,
Sandra Reyes	
Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY

2016

CYCLE PROGRAM

1 Research

AWARD MECHANISM

Individual Investigator Research Awards for Cancer in Children

APPLICATION ID

and Adolescents (IIRACCA) RP160022

APPLICATION ID R

Role of Cohesin in Hematopoiesis and Myeloid Leukemia in

APPLICATION TITLE
APPLICANT NAME

Children with Down Syndrome Pati, Debananda

ORGANIZATION

Baylor College of Medicine

PANEL NAME

16.1 Clinical / Translational Cancer Research (16.1 C/TCR)

Dategory	Compilance Regulterrant	Information	Attestation Dat
	RFA published in Texas Register	02/27/15	10/06/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/06/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/06/15
no no setat	Date application submitted	05/19/15	10/06/15
. Pre-Receipt	Method of submission	CARS	10/06/15
	Within receipt period	YES	10/06/15
	Appeal to submit application after CARS closed	N/A	10/06/15
	Appeal for late application submission accepted	N/A	10/06/15
	Administrative review notification	N/A	10/06/15
	Donation(s) made to CPRIT/foundation	NO	10/06/15
	Assigned to primary reviewers	N/A	10/06/15
. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/06/15
nd Assignment	Primary Reviewer 1 COI signed	N/A	10/06/15
	Primary Reviewer 2 COI signed	N/A	10/06/15
	Primary Reviewer 3 COI signed	N/A	10/06/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/06/15
	Primary Reviewer 1 critique submitted	N/A	10/06/15
	Primary Reviewer 2 critique submitted	N/A	10/06/15
	Primary Reviewer 3 critique submitted	N/A	10/06/15
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/06/15
valuation	COI indicated by non-primary reviewer	N/A	10/06/15
	Preliminary Evaluation score summary sent to Chair	N/A	10/06/15
	Recommended for full review	N/A	10/06/15
	Applicant notified of outcome	N/A	10/06/15
	Assigned to primary reviewers	08/25/15	10/06/15
	Primary Reviewer 1 COI signed	06/23/15	10/06/15
	Primary Reviewer 2 COI signed	06/19/15	10/06/15
	Primary Reviewer 3 COI signed	06/30/15	10/06/15
	Primary (Advocate) Reviewer 4 COI signed	07/29/15	10/06/15
	Primary Reviewer 1 critique submitted	09/28/15	10/06/15
	Primary Reviewer 2 critique submitted	09/13/15	10/06/15
	Primary Reviewer 3 critique submitted	09/21/15	10/06/15
, Peer Review	Primary (Advocate) Reviewer 4 critique submitted	09/14/15	10/06/15
/leeting	COI indicated by non-primary reviewer	NONE	10/13/15
	COI recused from participation	N/A	10/13/15
	Discussed at Peer Review Meeting	YES	10/06/15
	Peer Review Meeting	09/29/15	10/06/15
	Post review statements signed	10/12/15	10/13/15
	Third Party Observer Report	10/07/15	10/14/15
	Score report delivered to CSO	10/19/15	10/23/15
	Recommended for SRC Review	YES	10/13/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
. Final SRC	SRC Meeting	10/23/15	10/27/15
ecommendation	Third Party Observer Report	10/27/15	10/28/15
econimendadon	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation	M. Kripke	11/03/15
. PIC Review	PIC review meeting	11/03/15	11/03/15
		YES YES	11/03/15
	Recommended for grant award	DATE	11/03/13
	CEO Notification to Oversight Committee	_	
	COI required from posticipation	NAME OF NONE	
	COI recused from participation	YES/NO or N/A	
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
ommittee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CEO AFFIDAVIT Application RP160023 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Basic Cancer Research Panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the the day of November	e undersigned authority, on, 2015,
by WAYNE R. ROBERTS.	
Sandra Reves	
Notary Public, State of Texas	
	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

2016 CYCLE PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160023

Investigating the Genetic and Molecular Mechanisms APPLICATION TITLE

Underlying RAS/ERK Substrate Network

APPLICANT NAME Arur, Swathi

The University of Texas M. D. Anderson Cancer Center ORGANIZATION

PANEL NAME 16.1 Basic Cancer Research-2 (16.1 BCR-2)

Eategory	Complinace Regultement	Information	Attention Date
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
	Date application submitted	05/15/15	10/09/15
. Pre-Receipt	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	07/20/15	10/09/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
and Assignment	Primary Reviewer 1 COI signed	06/30/15	10/09/15
	Primary Reviewer 2 COI signed	06/19/15	10/09/15
	Primary Reviewer 3 COI signed	07/21/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	07/22/15	10/09/15
	Primary Reviewer 2 critique submitted	08/07/15	10/09/15
	Primary Reviewer 3 critique submitted	08/12/15	10/09/15
J. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
S. Preliminary Evaluation	COI indicated by non-primary reviewer	NONE	10/09/15
evaluation	Preliminary Evaluation score summary sent to Chair	08/12/15	10/09/15
		YES	10/09/15
	Recommended for full review	09/01/15	10/09/15
	Applicant notified of outcome	08/21/15	10/09/15
	Assigned to primary reviewers	06/30/15	10/09/15
	Primary Reviewer 1 COI signed	06/19/15	10/09/15
	Primary Reviewer 2 COI signed	07/21/15	10/09/15
	Primary Reviewer 3 COI signed	08/06/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	09/27/15	10/09/15
	Primary Reviewer 1 critique submitted		10/09/15
	Primary Reviewer 2 critique submitted	09/26/15	10/09/15
4. Peer Review	Primary Reviewer 3 critique submitted	10/01/15	
Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/12/15	10/09/15
	COI indicated by non-primary reviewer	NONE	10/09/15
	COI recused from participation	N/A	10/09/15
	Discussed at Peer Review Meeting	YES	10/09/15
	Peer Review Meeting	10/05/15	10/09/15
	Post review statements signed	10/11/15	10/14/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/09/15
	COI Indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
e nie n	COI recused from participation	M. Kripke	11/03/15
6. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CEO AFFIDAVIT Application RP160030 Individual Investigator Research Awards for Prevention and Early Detection

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Prevention and Early Detection* Request for Applications (RFA). CPRIT received 45 applications for this RFA, including 1 that was later withdrawn. This application was assigned to the Cancer Prevention Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas

County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on

the 5th day of November

, 2015,

by WAYNE R. ROBERTS.

Sandra Reves

Notary Public, State of Texas

SANDRA J. REYES
Notary Public, State of Texas
My Commission Expires
SEPTEMBER 30, 2017
Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2016 CYCLE PROGRAM Research

AWARD MECHANISM Endowment of the Control of the Con

Early Detection (IIRAP)

APPLICATION ID

A Randomized Controlled Trial (RCT) of Patient Navigation APPLICATION TITLE for Lung Cancer Screening in an Urban Safety-Net System

APPLICANT NAME

The University of Texas Southwestern Medical Center ORGANIZATION PANEL NAME 16.1 Cancer Prevention Research (16.1 CPR)

Category	Compliance Regulrement	Information	Attestation Date
	RFA published in Texas Register	02/27/15	10/09/15
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
	Date application submitted	05/19/15	10/09/15
	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	N/A	10/09/15
	Applicant notified of review panel assignment	06/30/15	10/09/15
	Primary Reviewer 1 COI signed	N/A	10/09/15
	Primary Reviewer 2 COI signed	N/A	10/09/15
	Primary Reviewer 3 COI signed	N/A	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	N/A	10/09/15
	Primary Reviewer 2 critique submitted	N/A	10/09/15
	Primary Reviewer 3 critique submitted	N/A	10/09/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
Evaluation	COI indicated by non-primary reviewer	N/A	10/09/15
	Preliminary Evaluation score summary sent to Chair	N/A	10/09/15
	Recommended for full review	N/A	10/09/15
	Applicant notified of outcome	N/A	10/09/15
	Assigned to primary reviewers	07/16/15	10/09/15
	Primary Reviewer 1 COI signed	07/09/15	10/09/15
	Primary Reviewer 2 COI signed	07/06/15	10/09/15
	Primary Reviewer 3 COI signed	06/22/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	06/15/15	10/09/15
	Primary Reviewer 1 critique submitted	08/19/15	10/09/15
	Primary Reviewer 2 critique submitted	09/18/15	10/09/15
	Primary Reviewer 3 critique submitted	09/08/15	10/09/15
4. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	09/21/15	10/09/15
Meeting	COI indicated by non-primary reviewer	Barlow, William	10/09/15
	COI recused from participation	YES	10/09/15
	Discussed at Peer Review Meeting	YES	10/09/15
	Peer Review Meeting	09/30/15	10/09/15
	Post review statements signed	10/05/15	10/22/15
	Third Party Observer Report	10/07/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/09/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
6. PIC Review	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation	M. Kripke	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
7. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME OF NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Hadronity to dayonce rains requested	1120/110	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CEO AFFIDAVIT Application RP160035 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Cancer Biology panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 5th day of November , 2015, by WAYNE R. ROBERTS.

Sandra Reyes
Notary Public, State of Texas

SANDRA J. REYES
Notary Public, State of Texas
My Commission Expires
SEPTEMBER 30, 2017
Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160035

APPLICATION TITLE

The Role of Prdm16 and Histone H3 Lysine 9

Application Title

Application Title

Application Title

Methyltransferase Complex in MDS

APPLICANT NAME Nakada, Daisuke
ORGANIZATION Baylor College of Medicine
PANEL NAME 16.1 Cancer Biology (16.1 CB)

Category	Compliance Regulrement	Information	Attestation Dat
	RFA published in Texas Register	02/27/15	10/12/15
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	03/20/15	10/12/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/12/15
	Date application submitted	05/14/15	10/12/15
	Method of submission	CARS	10/12/15
	Within receipt period	YES	10/12/15
	Appeal to submit application after CARS closed	N/A	10/12/15
	Appeal for late application submission accepted	N/A	10/12/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/12/15
	Donation(s) made to CPRIT/foundation	NO	10/12/15
	Assigned to primary reviewers	07/20/15	10/12/15
	Applicant notified of review panel assignment	06/30/15	10/12/15
	Primary Reviewer 1 COI signed	07/03/15	10/12/15
	Primary Reviewer 2 COI signed	06/18/15	10/12/15
	Primary Reviewer 3 COI signed	06/24/15	10/12/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/12/15
	Primary Reviewer 1 critique submitted	08/06/15	10/12/15
	Primary Reviewer 2 critique submitted	07/27/15	10/12/15
	Primary Reviewer 3 critique submitted	08/06/15	10/12/15
3. Preliminary Evaluation	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/12/15
	COI indicated by non-primary reviewer	NONE	10/12/15
	Preliminary Evaluation score summary sent to Chair	08/10/15	10/12/15
	Recommended for full review	YES	10/12/15
	Applicant notified of outcome	09/01/15	10/12/15
	Assigned to primary reviewers	08/18/15	10/12/15
	Primary Reviewer 1 COI signed	07/03/15	10/12/15
	Primary Reviewer 2 COI signed	06/18/15	10/12/15
	Primary Reviewer 3 COI signed	06/18/15	10/12/15
	Primary (Advocate) Reviewer 4 COI signed	06/19/15	10/12/15
4. Peer Review		09/30/15	10/12/15
	Primary Reviewer 1 critique submitted	09/15/15	10/12/15
	Primary Reviewer 2 critique submitted	09/28/15	10/12/15
	Primary Reviewer 3 critique submitted Primary (Advocate) Reviewer 4 critique submitted	09/05/15	10/12/15
Meeting		NONE	10/12/15
	COI indicated by non-primary reviewer	N/A	10/12/15
	COI recused from participation	YES	10/12/15
	Discussed at Peer Review Meeting	_	
	Peer Review Meeting	10/07/15	10/12/15
	Post review statements signed	10/15/15	
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/12/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
5. PIC Review	COI recused from participation	M. Kripke	11/03/15
A FIC NEVICW	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
7. Oversight Committee Approval	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications,

The identity of the attesting party is retained by CPRIT.



CEO AFFIDAVIT Application RP160051 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas	
County of Travis	
SWORN to and SUBSCRIBED before me, the 5th day of November	
by WAYNE R. ROBERTS.	
Sandra Reyes	
Notary Public, State of Texas	
	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	(1) After the collection of the forest the collection of the colle

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

2016 FY CYCLE PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID

-Improving Contrast for Antibody-Based Tumor Detection Using PET APPLICATION TITLE

APPLICANT NAME Ward, Elizabeth

ORGANIZATION Texas A&M University System Health Science Center 16.1 Imaging Technology and Informatics (16.1 ITI) PANEL NAME

Category	Compliance Requirement	Information	Attestation Det
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
	Date application submitted	05/12/15	10/09/15
L. Pre-Receipt	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	07/22/15	10/09/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
and Assignment	Primary Reviewer 1 COI signed	07/06/15	10/09/15
	Primary Reviewer 2 COI signed	06/30/15	10/09/15
	Primary Reviewer 3 COI signed	07/07/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	07/29/15	10/09/15
	Primary Reviewer 2 critique submitted	07/24/15	10/09/15
	Primary Reviewer 3 critique submitted	08/05/15	10/09/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
Evaluation	COI indicated by non-primary reviewer	NONE	10/09/15
cvaruation		08/11/15	10/09/15
	Preliminary Evaluation score summary sent to Chair Recommended for full review	YES	10/09/15
		09/01/15	10/09/15
	Applicant notified of outcome	08/17/15	10/09/15
	Assigned to primary reviewers	07/06/15	10/09/15
	Primary Reviewer 1 COI signed	06/30/15	10/09/15
	Primary Reviewer 2 COI signed	07/07/15	10/09/15
	Primary Reviewer 3 COI signed	_	
	Primary (Advocate) Reviewer 4 COI signed	07/13/15	10/09/15
	Primary Reviewer 1 critique submitted	09/25/15	10/09/15
	Primary Reviewer 2 critique submitted	09/20/15	10/09/15
4. Peer Review	Primary Reviewer 3 critique submitted	09/23/15	10/09/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/23/15	10/09/15
	COI indicated by non-primary reviewer	NONE	10/09/15
	COI recused from participation	N/A	10/09/15
	Discussed at Peer Review Meeting	YES	10/09/15
	Peer Review Meeting	10/01/15	10/09/15
	Post review statements signed	10/08/15	10/09/15
	Third Party Observer Report	10/07/15	10/14/15
	Score report delivered to CSO	10/19/15	10/23/15
	Recommended for SRC Review	YES	10/09/15
	COI Indicated by SRC member	NONE	10/28/15
	COI recused from participation	N/A	10/28/15
5. Final SRC	SRC Meeting	10/23/15	10/28/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/28/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
5. PIC Review	COI recused from participation	M. Kripke	11/03/15
o. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CEO AFFIDAVIT Application RP160054 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Basic Cancer Research Panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO. Cancer Prevention and Research Institute of Texas

ndersigned authority, on, 2015,
_
SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

CYCLE 1 PROGRAM

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160054

The CTC Circulator Phenotype: Insights into Mechanisms of APPLICATION TITLE Breast Cancer Dormancy

APPLICANT NAME Marchetti, Dario ORGANIZATION Baylor College of Medicine

16.1 Basic Cancer Research-2 (16.1 BCR-2) PANEL NAME

Category	Compliance Requirement	information	Attestation 0
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
	Date application submitted	04/27/15	10/09/15
L. Pre-Receipt	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	07/20/15	10/09/15
. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
nd Assignment	Primary Reviewer 1 COI signed	06/30/15	10/09/15
	Primary Reviewer 2 COI signed	07/08/15	10/09/15
	Primary Reviewer 3 COI signed	07/21/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	07/22/15	10/09/15
	Primary Reviewer 2 critique submitted	08/07/15	10/09/15
	Primary Reviewer 3 critique submitted	08/12/15	10/09/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
valuation	COI indicated by non-primary reviewer	NONE	10/09/15
.valuation	Preliminary Evaluation score summary sent to Chair	08/12/15	10/09/15
	Recommended for full review	YES YES	10/09/15
			10/09/15
	Applicant notified of outcome	09/01/15	10/09/15
	Assigned to primary reviewers		
	Primary Reviewer 1 COI signed	07/21/15	10/09/15
	Primary Reviewer 2 COI signed	06/30/15	10/09/15
	Primary Reviewer 3 COI signed	07/01/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	08/27/15	10/09/15
	Primary Reviewer 1 critique submitted	10/01/15	10/09/15
	Primary Reviewer 2 critique submitted	09/11/15	10/09/15
1. Peer Review	Primary Reviewer 3 critique submitted	09/20/15	10/09/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/28/15	10/09/15
	COI indicated by non-primary reviewer	NONE	10/09/15
	COI recused from participation	N/A	10/09/15
	Discussed at Peer Review Meeting	YES	10/09/15
	Peer Review Meeting	10/05/15	10/09/15
	Post review statements signed	10/11/15	10/14/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/09/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
nie nouteur	COI recused from participation	M. Kripke	11/03/15
i. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	_

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CEO AFFIDAVIT Application RP160089 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Basic Cancer Research Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the	e undersigned authority, on
the 5th day of November	, 2015,
by WAYNE R. ROBERTS.	
Sandra Reyes	
Notary Public, State of Texas	
	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160089

APPLICATION TITLE

Carbamoyl Phosphate Synthase-1: A New Metabolic

Liability in Non-Small Cell Lung Cancers

APPLICANT NAME DeBerardinis, Ralph

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME 16.1 Basic Cancer Research-1 (16,1 BCR-1)

Category	Compliance Requirement	toformution	Attestation Dat
	RFA published in Texas Register	02/27/15	10/11/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/11/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/11/15
	Date application submitted	05/13/15	10/11/15
. Pre-Receipt	Method of submission	CARS	10/11/15
	Within receipt period	YES	10/11/15
	Appeal to submit application after CARS closed	N/A	10/11/15
	Appeal for late application submission accepted	N/A	10/11/15
	Administrative review notification	N/A	10/11/15
	Donation(s) made to CPRIT/foundation	NO	10/11/15
	Assigned to primary reviewers	07/17/15	10/11/15
. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/11/15
nd Assignment	Primary Reviewer 1 COI signed	07/03/15	10/11/15
	Primary Reviewer 2 COI signed	07/02/15	10/11/15
	Primary Reviewer 3 COI signed	07/01/15	10/11/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/11/15
	Primary Reviewer 1 critique submitted	08/03/15	10/11/15
	Primary Reviewer 2 critique submitted	07/28/15	10/11/15
	Primary Reviewer 3 critique submitted	07/23/15	10/11/15
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/11/15
valuation	COI indicated by non-primary reviewer	NONE	10/11/15
valuation	Preliminary Evaluation score summary sent to Chair	08/06/15	10/11/15
	Recommended for full review	YES	10/11/15
	Applicant notified of outcome	09/01/15	10/11/15
		08/11/15	10/11/15
- 4	Assigned to primary reviewers	07/03/15	10/11/15
	Primary Reviewer 1 COI signed	07/03/15	10/11/15
	Primary Reviewer 2 COI signed		
	Primary Reviewer 3 COI signed	07/01/15	10/11/15
	Primary (Advocate) Reviewer 4 COI signed	06/15/15	
	Primary Reviewer 1 critique submitted	09/28/15	10/11/15
	Primary Reviewer 2 critique submitted	09/02/15	10/11/15
I. Peer Review	Primary Reviewer 3 critique submitted	08/22/15	10/11/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	08/29/15	10/11/15
· ·	COI indicated by non-primary reviewer	NONE	10/11/15
	COI recused from participation	N/A	10/11/15
	Discussed at Peer Review Meeting	YES	10/11/15
	Peer Review Meeting	10/06/15	10/11/15
	Post review statements signed	10/12/15	10/14/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/11/15
	COI Indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
i. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation	M. Kripke	11/03/15
i, PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME OF NONE	
	COI recused from participation	YES/NO or N/A	7
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
*	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

The identity of the attesting party is retained by CPRIT.



CEO AFFIDAVIT Application RP160097 Research Training Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Research Training Awards* Request for Applications (RFA). CPRIT received 13 applications for this RFA. This application was assigned to the Cancer Prevention Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on

the 5th day of November

. 2015,

by WAYNE R. ROBERTS.

Sandra Reyes

Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Research Training Awards (RTA)

APPLICATION ID RP160097

APPLICATION TITLE

Cancer Prevention Post-Graduate Training Program in

APPLICATION TITLE Integrative Epidemiology

APPLICANT NAME Spitz, Margaret

ORGANIZATION Baylor College of Medicine

PANEL NAME 16.1 Cancer Prevention Research (16.1 CPR)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
. Pre-Receipt	Date application submitted	05/14/15	10/09/15
. Tre-necespe	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	N/A	10/09/15
. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
and Assignment	Primary Reviewer 1 COI signed	N/A	10/09/15
	Primary Reviewer 2 COI signed	N/A	10/09/15
	Primary Reviewer 3 COI signed	N/A	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	N/A	10/09/15
	Primary Reviewer 2 critique submitted	N/A	10/09/15
	Primary Reviewer 3 critique submitted	N/A	10/09/15
3. PrelimInary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
valuation	COI indicated by non-primary reviewer	N/A	10/09/15
	Preliminary Evaluation score summary sent to Chair	N/A	10/09/15
	Recommended for full review	N/A	10/09/15
	Applicant notified of outcome	N/A	10/09/15
	Assigned to primary reviewers	07/16/15	10/09/15
	Primary Reviewer 1 COI signed	06/25/15	10/09/15
	Primary Reviewer 2 COI signed	07/06/15	10/09/15
	Primary Reviewer 3 COI signed	06/25/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	06/15/15	10/09/15
	Primary Reviewer 1 critique submitted	08/29/15	10/09/15
	Primary Reviewer 2 critique submitted	09/24/15	10/09/15
1. Peer Review	Primary Reviewer 3 critique submitted	09/30/15	10/09/15
Viceting	Primary (Advocate) Reviewer 4 critique submitted	09/23/15	10/09/15
	COI indicated by non-primary reviewer	Martinez, Maria	10/09/15
	COI recused from participation	YES	10/09/15
	Discussed at Peer Review Meeting	YES	10/09/15
	Peer Review Meeting	09/30/15	10/09/15
	Post review statements signed	10/05/15	10/22/15
	Third Party Observer Report	10/07/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/09/15
	COI Indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
5. PIC Review	COI recused from participation	N/A	11/03/15
	PIC review meeting	11/03/15	11/03/15
10.000	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	VES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	



CEO AFFIDAVIT Application RP160121 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Clinical and Translational Cancer Research and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the 5 th day of November by WAYNE R. ROBERTS.	the undersigned authority, on, 2015,
Sandra Reyes	
Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2016 CYCLE 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160121

APPLICATION TITLE Clinical Safety and Efficacy of Third party, Fucosylated, Cord Blood Derived Regulatory T Cells to Prevent Graft Versus Host Disease

APPLICANT NAME Parmar, Simrit

ORGANIZATION The University of Texas M. D., Anderson Cancer Center
PANEL NAME 16,1 Clinical / Translational Cancer Research (16,1 C/TCR)

Category	Compliance Requirement	Information	Attestation Do
	RFA published in Texas Register	02/27/15	10/07/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/07/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/07/15
	Date application submitted	05/18/15	10/07/15
l. Pre-Receipt	Method of submission	CARS	10/07/15
	Within receipt period	YES	10/07/15
	Appeal to submit application after CARS closed	N/A	10/07/15
	Appeal for late application submission accepted	N/A	10/07/15
	Administrative review notification	N/A	10/07/15
	Donation(s) made to CPRIT/foundation	NO	10/07/15
	Assigned to primary reviewers	07/23/15	10/07/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/07/15
and Assignment	Primary Reviewer 1 COI signed	06/23/15	10/07/15
	Primary Reviewer 2 COI signed	06/26/15	10/07/15
	Primary Reviewer 3 COI signed	07/15/15	10/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/07/15
	Primary Reviewer 1 critique submitted	08/03/15	10/07/15
	Primary Reviewer 2 critique submitted	08/13/15	10/07/15
	Primary Reviewer 3 critique submitted	08/15/15	10/07/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/07/15
Evaluation	COI indicated by non-primary reviewer	NONE	10/07/15
	Preliminary Evaluation score summary sent to Chair	08/17/15	10/07/15
	Recommended for full review	YES	10/07/15
	Applicant notified of outcome	09/01/15	10/07/15
	Assigned to primary reviewers	08/25/15	10/07/15
	Primary Reviewer 1 COI signed	06/23/15	10/07/15
	Primary Reviewer 2 COI signed	06/26/15	10/07/15
	Primary Reviewer 3 COI signed	07/15/15	10/07/15
	Primary (Advocate) Reviewer 4 COI signed	08/27/15	10/07/15
	Primary Reviewer 1 critique submitted	08/31/15	10/07/15
	Primary Reviewer 2 critique submitted	09/21/15	10/07/15
	Primary Reviewer 3 critique submitted	09/28/15	10/07/15
1. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	09/17/15	10/07/15
Meeting		NONE	10/13/15
	COI indicated by non-primary reviewer		
	COI recused from participation	N/A YES	10/13/15
	Discussed at Peer Review Meeting		_
	Peer Review Meeting	09/29/15	10/07/15
	Post review statements signed	10/12/15	10/13/15
	Third Party Observer Report	10/07/15	10/14/15
	Score report delivered to CSO	10/19/15	10/23/15
	Recommended for SRC Review	YES	10/07/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
i. PIC Review	COI recused from participation	M. Kripke	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CEO AFFIDAVIT Application RP160124 Individual Investigator Research Awards for Prevention and Early Detection

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Prevention and Early Detection* Request for Applications (RFA). CPRIT received 45 applications for this RFA, including 1 that was later withdrawn. This application was assigned to the Cancer Prevention Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas

County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on

the 5th day of November

, 2015,

by WAYNE R. ROBERTS.

Sandra Reyes

Notary Public, State of Texas

SANDRA J. REYES
Notary Public, State of Texas
My Commission Expires
SEPTEMBER 30, 2017

Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

2016 FY CYCLE PROGRAM Research

Individual Investigator Research Awards for Prevention and Early Detection (IIRAP) AWARD MECHANISM

APPLICATION ID

Chemoprevention of Colon Cancer by Anti-inflammatory APPLICATION TITLE

Blockade Using Neem APPLICANT NAME Wargovich, Michael

The University of Texas Health Science Center at San ORGANIZATION

Antonio 16₄1 Cancer Prevention Research (16.1 CPR) PANEL NAME

Category	Compliance Requirement	Information	Attentation Date
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
L. Pre-Receipt	Date application submitted	05/19/15	10/09/15
i. Pre-Receipt	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	N/A	10/09/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
and Assignment	Primary Reviewer 1 COI signed	N/A	10/09/15
	Primary Reviewer 2 COI signed	N/A	10/09/15
	Primary Reviewer 3 COI signed	N/A	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	N/A	10/09/15
	Primary Reviewer 2 critique submitted	N/A	10/09/15
	Primary Reviewer 3 critique submitted	N/A	10/09/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
Evaluation	COI indicated by non-primary reviewer	N/A	10/09/15
	Preliminary Evaluation score summary sent to Chair	N/A	10/09/15
	Recommended for full review	N/A	10/09/15
	Applicant notified of outcome	N/A	10/09/15
	Assigned to primary reviewers	07/16/15	10/09/15
	Primary Reviewer 1 COI signed	06/30/15	10/09/15
	Primary Reviewer 2 COI signed	07/01/15	10/09/15
	Primary Reviewer 2 COI signed	06/24/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	06/18/15	10/09/15
	Primary Reviewer 1 critique submitted	09/21/15	10/09/15
	Primary Reviewer 2 critique submitted	09/17/15	10/09/15
	Primary Reviewer 3 critique submitted	09/08/15	10/09/15
1. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	09/17/15	10/09/15
Vieeting	COI indicated by non-primary reviewer	NONE	10/09/15
	COI recused from participation	N/A	10/09/15
	Discussed at Peer Review Meeting	YES	10/09/15
		09/30/15	10/09/15
	Peer Review Meeting	10/05/15	10/22/15
	Post review statements signed	10/03/15	10/14/15
	Third Party Observer Report		_
	Score report delivered to CSO Recommended for SRC Review	10/19/15	10/22/15
		YES	10/09/15
	COI indicated by SRC member	NONE	_
ri Jene	COI recused from participation	N/A	10/27/15
5. Final SRC Recommendation	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI Indicated by PIC member	NONE	11/03/15
. PIC Review	COI recused from participation	M. Kripke	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	-
	COI indicated by Oversight Committee member	NAME OF NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CEO AFFIDAVIT Application RP160145 Individual Investigator Research Awards for Prevention and Early Detection

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Prevention and Early Detection* Request for Applications (RFA). CPRIT received 45 applications for this RFA, including 1 that was later withdrawn. This application was assigned to the Cancer Prevention Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Røberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on

the 5th day of November

. 2015,

by WAYNE R. ROBERTS.

Sandra Reyes

Notary Public, State of Texas

SANDRA J. REYES
Notary Public, State of Texas
My Commission Expires
SEPTEMBER 30, 2017

Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY CYCLE 1 PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)

APPLICATION ID RP160145

Early Detection of Ovarian Cancer with Tumor Associated APPLICATION TITLE

Proteins and Autoantibodies

APPLICANT NAME Bast, Robert

The University of Texas M. D. Anderson Cancer Center ORGANIZATION PANEL NAME 16.1 Cancer Prevention Research (16,1 CPR)

Category	Compliance Requirement	Information	Attestation Dat
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
	Date application submitted	05/20/15	10/09/15
1. Pre-Receipt	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	N/A	10/09/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
and Assignment	Primary Reviewer 1 COI signed	N/A	10/09/15
	Primary Reviewer 2 COI signed	N/A	10/09/15
	Primary Reviewer 3 COI signed	N/A	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	N/A	10/09/15
	Primary Reviewer 2 critique submitted	N/A	10/09/15
	Primary Reviewer 3 critique submitted	N/A	10/09/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
Evaluation	COI indicated by non-primary reviewer	N/A	10/09/15
	Preliminary Evaluation score summary sent to Chair	N/A	10/09/15
	Recommended for full review	N/A	10/09/15
	Applicant notified of outcome	N/A	10/09/15
	Assigned to primary reviewers	07/16/15	10/09/15
	Primary Reviewer 1 COI signed	06/24/15	10/09/15
	Primary Reviewer 2 COI signed	06/19/15	10/09/15
	Primary Reviewer 3 COI signed	06/23/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	06/18/15	10/09/15
		09/08/15	10/09/15
	Primary Reviewer 1 critique submitted Primary Reviewer 2 critique submitted	09/15/15	10/09/15
		09/23/15	10/09/15
	Primary Reviewer 3 critique submitted Primary (Advocate) Reviewer 4 critique submitted	09/11/15	10/09/15
4. Peer Review		Kushi, Lawrence	10/09/15
Meeting	COI indicated by non-primary reviewer COI recused from participation	YES YES	10/09/15
		Li, Christopher	10/09/15
	COI indicated by non-primary reviewer	YES	
	COI recused from participation	YES	10/09/15
	Discussed at Peer Review Meeting		10/09/15
	Peer Review Meeting	09/30/15	10/09/15
	Post review statements signed	10/05/15	10/22/15
	Third Party Observer Report	10/07/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/09/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
5. PIC Review	COI recused from participation	M. Kripke	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
A. 24	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	il i
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CEO AFFIDAVIT Application RP160150 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Røberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
	a undergianed authority on
sworn to and subscribed before me, the	, 2015,
by WAYNE R. ROBERTS.	
Sandra Reyes	
Notary Public, State of Texas	
Trotally Tubile, State of Tollas	SANDRA J. REYES
	Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Resear

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160150

KF160130

Radiogenomic Screen to Identify Novel Proliferation-APPLICATION TITLE associated Glioblastoma Genomic Therapeutic Targets:

Discovery and Mechanistic Validation Study

APPLICANT NAME

Colen, Rivka

ORGANIZATION PANEL NAME

The University of Texas M. D. Anderson Cancer Center 16.1 Imaging Technology and Informatics (16.1 ITI)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	02/27/15	10/09/15
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
	Date application submitted	05/20/15	10/09/15
	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
2. Recelpt, Referral, and Assignment	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	07/22/15	10/09/15
	Applicant notified of review panel assignment	06/30/15	10/09/15
	Primary Reviewer 1 COI signed	07/03/15	10/09/15
	Primary Reviewer 2 COI signed	06/23/15	10/09/15
	Primary Reviewer 3 COI signed	07/02/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
1	Primary Reviewer 1 critique submitted	08/11/15	10/09/15
	Primary Reviewer 2 critique submitted	07/30/15	10/09/15
	Primary Reviewer 3 critique submitted	08/03/15	10/09/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
Evaluation	COI indicated by non-primary reviewer	NONE	10/09/15
	Preliminary Evaluation score summary sent to Chair	08/11/15	10/09/15
	Recommended for full review	YES	10/09/15
	Applicant notified of outcome	09/01/15	10/09/15
	Assigned to primary reviewers	08/17/15	10/09/15
	Primary Reviewer 1 COI signed	07/03/15	10/09/15
	Primary Reviewer 2 COI signed	06/23/15	10/09/15
	Primary Reviewer 3 COI signed	07/02/15	10/09/15
4. Peer Review Meeting	Primary (Advocate) Reviewer 4 COI signed	07/13/15	10/09/15
	Primary Reviewer 1 critique submitted	09/30/15	10/09/15
	Primary Reviewer 2 critique submitted	09/19/15	10/09/15
	Primary Reviewer 3 critique submitted	09/30/15	10/09/15
	Primary (Advocate) Reviewer 4 critique submitted	09/24/15	10/09/15
	COI indicated by non-primary reviewer	NONE	10/09/15
	COI recused from participation	N/A YES	10/09/15
	Discussed at Peer Review Meeting	_	10/09/15
	Peer Review Meeting	10/01/15	10/09/15
	Post review statements signed	10/08/15	10/14/15
	Third Party Observer Report	10/19/15	10/23/15
	Score report delivered to CSO Recommended for SRC Review	YES YES	10/09/15
		NONE	10/28/15
	COI indicated by SRC member COI recused from participation	N/A	10/28/15
5. Final SRC Recommendation	SRC Meeting	10/23/15	10/28/15
	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/28/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation	M. Kripke	11/03/15
5. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
7. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	11/18/15	42
	Award approved by Oversight Committee	YES/NO	4
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CEO AFFIDAVIT Application RP160157 Research Training Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Research Training Awards* Request for Applications (RFA). CPRIT received 13 applications for this RFA. This application was assigned to the Basic Cancer Research Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas

County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on

the 5th day of November

, 2015,

by WAYNE R. ROBERTS.

Sandra Reye

Notary Public, State of Texas

SANORA J. REYES
Notary Public, State of Texas
My Commission Expires
SEPTEMBER 30, 2017

Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY

CYCLE

1

PROGRAM

AWARD MECHANISM Research Training Awards (RTA)

APPLICATION ID

RP160157

APPLICATION TITLE Cancer Intervention and Prevention Discoveries Program

APPLICANT NAME

White, Michael

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME 16.1 Basic Cancer Research-1 (16.1 BCR-1)

Category	Compliance Requirement	Information	Attestation Out
	RFA published in Texas Register	02/27/15	10/11/15
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	03/20/15	10/11/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/11/15
	Date application submitted	05/18/15	10/11/15
	Method of submission	CARS	10/11/15
	WithIn receipt period	YES	10/11/15
	Appeal to submit application after CARS closed	N/A	10/11/15
	Appeal for late application submission accepted	N/A	10/11/15
2. Receipt, Referral, and Assignment	Administrative review notification	06/16/15	10/11/15
	Donation(s) made to CPRIT/foundation	NO	10/11/15
	Assigned to primary reviewers	N/A	10/11/15
	Applicant notified of review panel assignment	06/30/15	10/11/15
	Primary Reviewer 1 COI signed	N/A	10/11/15
	Primary Reviewer 2 COI signed	N/A	10/11/15
	Primary Reviewer 3 COI signed	N/A	10/11/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/11/15
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	10/11/15
	Primary Reviewer 2 critique submitted	N/A	10/11/15
	Primary Reviewer 3 critique submitted	N/A	10/11/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/11/15
	COI indicated by non-primary reviewer	N/A	10/11/15
	Preliminary Evaluation score summary sent to Chair	N/A	10/11/15
	Recommended for full review	N/A	10/11/15
	Applicant notified of outcome	N/A	10/11/15
	Assigned to primary reviewers	08/11/15	10/11/15
	Primary Reviewer 1 COI signed	06/18/15	10/11/15
	Primary Reviewer 2 COI signed	06/24/15	10/11/15
	Primary Reviewer 2 COI signed	07/02/15	10/11/15
4. Peer Review Meeting	Primary (Advocate) Reviewer 4 COI signed	06/18/15	10/11/15
	Primary (Advocate) Reviewer 4 Cot signed	09/20/15	10/11/15
	Primary Reviewer 2 critique submitted	09/24/15	10/11/15
	Primary Reviewer 3 critique submitted	09/09/15	10/11/15
	Primary (Advocate) Reviewer 4 critique submitted	08/31/15	10/11/15
	COI indicated by non-primary reviewer	NONE	10/11/15
	COI recused from participation	N/A	
		YES	10/11/15
	Discussed at Peer Review Meeting	10/06/15	10/11/15
	Peer Review Meeting		10/11/15
	Post review statements signed	10/12/15	10/14/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/11/15
	COI Indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC Recommendation	SRC Meeting	10/23/15	10/27/15
	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
6. PIC Review	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI Indicated by PIC member	NONE	11/03/15
	COI recused from participation	N/A	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
7. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	0
	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



CEO AFFIDAVIT Application RP160169 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn,. This application was assigned to the Basic Cancer Research Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, to	he undersigned authority, on
the 5th day of November by WAYNE R. ROBERTS.	, 2015,
A	
Sandra Reyes Notary Public, State of Texas	
notary Fublic, State of Texas	SANDRA J. REYES
	Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160169

APPLICATION TITLE Molecular Mechanism of NLRP12-mediated Regulation of

APPLICATION TITLE

Colorectal Cancer

APPLICANT NAME

Zaki, Hasan

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME 16.1 Basic Cancer Research-1 (16.1 BCR-1)

Category	Compliance Requirement	Information	Attentation Date
	RFA published in Texas Register	02/27/15	10/11/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/11/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/11/15
	Date application submitted	05/19/15	10/11/15
L. Pre-Receipt	Method of submission	CARS	10/11/15
	Within receipt period	YES	10/11/15
	Appeal to submit application after CARS closed	N/A	10/11/15
	Appeal for late application submission accepted	N/A	10/11/15
	Administrative review notification	N/A	10/11/15
	Donation(s) made to CPRIT/foundation	NO	10/11/15
	Assigned to primary reviewers	07/17/15	10/11/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/11/15
and Assignment	Primary Reviewer 1 COI signed	06/18/15	10/11/15
	Primary Reviewer 2 COI signed	07/02/15	10/11/15
	Primary Reviewer 3 COI signed	07/03/15	10/11/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/11/15
	Primary Reviewer 1 critique submitted	07/29/15	10/11/15
	Primary Reviewer 2 critique submitted	07/31/15	10/11/15
	Primary Reviewer 3 critique submitted	08/04/15	10/11/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/11/15
Evaluation	COI indicated by non-primary reviewer	NONE	10/11/15
Leaderon	Preliminary Evaluation score summary sent to Chair	08/06/15	10/11/15
	Recommended for full review	YES	10/11/15
	Applicant notified of outcome	09/01/15	10/11/15
	Assigned to primary reviewers	08/11/15	10/11/15
	Primary Reviewer 1 COI signed	07/03/15	10/11/15
	Primary Reviewer 2 COI signed	07/04/15	10/11/15
	Primary Reviewer 3 COI signed	07/02/15	10/11/15
	Primary (Advocate) Reviewer 4 COI signed	06/15/15	10/11/15
	Primary (Advocate) Neviewer 4 Consigned Primary Reviewer 1 critique submitted	09/28/15	10/11/15
	Primary Reviewer 2 critique submitted	09/25/15	10/11/15
	Primary Reviewer 3 critique submitted	09/10/15	10/11/15
4. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	08/28/15	10/11/15
Meeting	COI indicated by non-primary reviewer	NONE	10/11/15
	COI recused from participation	N/A	10/11/15
	Discussed at Peer Review Meeting	YES	10/11/15
	Peer Review Meeting	10/06/15	10/11/15
		10/12/15	10/14/15
	Post review statements signed	10/13/15	10/14/15
	Third Party Observer Report	10/19/15	10/22/15
	Score report delivered to CSO	YES	10/11/15
	Recommended for SRC Review	NONE	10/27/15
	COI Indicated by SRC member	N/A	10/27/15
	COI recused from participation	10/23/15	10/27/15
5. Final SRC	SRC Meeting		10/28/15
Recommendation	Third Party Observer Report	10/27/15 YES	10/27/15
	Recommended for grant award	_	10/28/15
	SRC Chair Notification to PIC and OC	10/26/15 NONE	11/03/15
	COI Indicated by PIC member		
6. PIC Review	COI recused from participation	M. Kripke	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160180 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Cancer Biology panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the undersigned authority, on the day of November by WAYNE R. ROBERTS.	, 2015,
	h-"
Notary Public, State of Texas SANDRA J. F. Notary Public, State	EVES to of Texas
Notary Public, Star My Commission SEPTEMBER 3 Notary without Bond	~~~

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

2016 CYCLE 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160180

Development of Therapeutics Targeting Truncated APPLICATION TITLE

Adenomatous Polyposis Coli (APC) as a Novel Prevention and

Intervention Strategy for Colorectal Cancer

APPLICANT NAME Shay, Jerry

The University of Texas Southwestern Medical Center ORGANIZATION

PANEL NAME 16.1 Cancer Biology (16.1 CB)

Category	Compliance Requirement	information	Attestation Date
	RFA published in Texas Register	02/27/15	10/12/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/12/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/12/15
	Date application submitted	05/13/15	10/12/15
1. Pre-Receipt	Method of submission	CARS	10/12/15
	Within receipt period	YES	10/12/15
	Appeal to submit application after CARS closed	N/A	10/12/15
	Appeal for late application submission accepted	N/A	10/12/15
	Administrative review notification	N/A	10/12/15
	Donation(s) made to CPRIT/foundation	NO	10/12/15
	Assigned to primary reviewers	N/A	10/12/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/12/15
and Assignment	Primary Reviewer 1 COI signed	N/A	10/12/15
, and the second	Primary Reviewer 2 COI signed	N/A	10/12/15
	Primary Reviewer 3 COI signed	N/A	10/12/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/12/15
	Primary Reviewer 1 critique submitted	N/A	10/12/15
	Primary Reviewer 2 critique submitted	N/A	10/12/15
	Primary Reviewer 3 critique submitted	N/A	10/12/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/12/15
Evaluation	COI indicated by non-primary reviewer	N/A	10/12/15
	Preliminary Evaluation score summary sent to Chair	N/A	10/12/15
	Recommended for full review	N/A	10/12/15
	Applicant notified of outcome	N/A	10/12/15
	Assigned to primary reviewers	08/18/15	10/12/15
	Primary Reviewer 1 COI signed	07/06/15	10/12/15
	Primary Reviewer 2 COI signed	06/30/15	10/12/15
	Primary Reviewer 3 COI signed	06/23/15	10/12/15
	Primary (Advocate) Reviewer 4 COI signed	06/19/15	10/12/15
	Primary (Advocate) Reviewer 4 Col signed Primary Reviewer 1 critique submitted	09/25/15	10/12/15
	Primary Reviewer 2 critique submitted	09/30/15	10/12/15
		09/29/15	10/12/15
4. Peer Review	Primary Reviewer 3 critique submitted Primary (Advocate) Reviewer 4 critique submitted	09/15/15	10/12/15
Meeting	COI indicated by non-primary reviewer	NONE	10/12/15
	COI recused from participation	N/A	10/12/15
	Discussed at Peer Review Meeting	YES	10/12/15
		10/07/15	10/12/15
	Peer Review Meeting	10/07/13	10/22/15
	Post review statements signed		10/14/15
	Third Party Observer Report	10/13/15	10/22/15
	Score report delivered to CSO	10/19/15 YES	10/12/15
	Recommended for SRC Review	NONE	10/12/15
	COI Indicated by SRC member	N/A	10/27/15
1	COI recused from participation		10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/28/15
Recommendation	Third Party Observer Report	10/27/15	10/27/15
	Recommended for grant award	YES	
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	
6. PIC Review	COI recused from participation	M. Kripke	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	-
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	VES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160183 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Basic Cancer Research Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Reberts,

County of Travis			
Jounty of Travis			
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SWORN to and SUBSCRIBED before me, the	e undersigned	-	2015
he 5th day of November		۷	2015,
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		Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017	1
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CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160183

Exploiting Molecular and Metabolic Dependencies to APPLICATION TITLE Optimize Personalized Therapeutic Approaches for

Melanomas

APPLICANT NAME Davies, Michael

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME 16_1 Basic Cancer Research-1 (16_1 BCR-1)

Category	Compliance Requirement	Information	Attestation Dat
	RFA published in Texas Register	02/27/15	10/11/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/11/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/11/15
. Dog Doggelan	Date application submitted	05/20/15	10/11/15
1. Pre-Receipt	Method of submission	CARS	10/11/15
	Within receipt period	YES	10/11/15
	Appeal to submit application after CARS closed	N/A	10/11/15
	Appeal for late application submission accepted	N/A	10/11/15
	Administrative review notification	N/A	10/11/15
	Donation(s) made to CPRIT/foundation	NO	10/11/15
	Assigned to primary reviewers	07/17/15	10/11/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/11/15
and Assignment	Primary Reviewer 1 COI signed	06/18/15	10/11/15
	Primary Reviewer 2 COI signed	D7/02/15	10/11/15
	Primary Reviewer 3 COI signed	07/04/15	10/11/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/11/15
	Primary Reviewer 1 critique submitted	08/05/15	10/11/15
	Primary Reviewer 2 critique submitted	07/31/15	10/11/15
	Primary Reviewer 3 critique submitted	08/04/15	10/11/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/11/15
Evaluation	COI indicated by non-primary reviewer	McMahon, Martin	10/11/15
	Preliminary Evaluation score summary sent to Chair	08/06/15	10/11/15
	Recommended for full review	YES	10/11/15
	Applicant notified of outcome	09/01/15	10/11/15
	Assigned to primary reviewers	08/11/15	10/11/15
	Primary Reviewer 1 COI signed	06/18/15	10/11/15
	Primary Reviewer 2 COI signed	07/02/15	10/11/15
	Primary Reviewer 3 COI signed	07/04/15	10/11/15
	Primary (Advocate) Reviewer 4 COI signed	06/15/15	10/11/15
	Primary Reviewer 1 critique submitted	08/25/15	10/11/15
	Primary Reviewer 2 critique submitted	09/02/15	10/11/15
4. Peer Review	Primary Reviewer 3 critique submitted	09/23/15	10/11/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	08/29/15	10/11/15
	COI indicated by non-primary reviewer	McMahon, Martin	10/11/15
	COI recused from participation	YES	10/11/15
	Discussed at Peer Review Meeting	YES	10/11/15
	Peer Review Meeting	10/06/15	10/11/15
	Post review statements signed	10/12/15	10/14/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/11/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
5. PIC Review	COI recused from participation	M. Krlpke	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE OF NORTH	+
	COI Indicated by Oversight Committee member	NAME OF NONE	
	COI recused from participation	VES/NO or N/A	
7. Oversight Committee Approval	Donation(s) made to CPRIT/foundation	YES/NO	+
	Presented to CPRIT Oversight Committee	11/18/15	
Committee Approval			
Committee Approval	Award approved by Oversight Committee Authority to advance funds requested	YES/NO YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160188 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Clinical and Translational Cancer Research and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Røberts,

County of Travis		
WORN to and SUBSCRIBE the 5th day of		•
he _5 m_ day of by WAYNE R. ROBERTS.	November	
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andra Reves		
Notary Public, State of Texas		
	2	SANDRA J. REYES
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	1	SEPTEMBER 30, 2017
		Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160188

APPLICATION TITLE Regulation of Infiltration and Function of Tumor-Resident CD8 T

Cells by IL-15

APPLICANT NAME Schluns, Kimberly

ORGANIZATION The University of Texas M, D, Anderson Cancer Center

PANEL NAME 16.1 Clinical / Translational Cancer Research (16.1 C/TCR)

Category	Compliance Requirement	Information	Attestation Do
	RFA published in Texas Register	02/27/15	10/07/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/07/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/07/15
	Date application submitted	05/18/15	10/07/15
. Pre-Receipt	Method of submission	CARS	10/07/15
	Within receipt period	YES	10/07/15
	Appeal to submit application after CARS closed	N/A	10/07/15
	Appeal for late application submission accepted	N/A	10/07/15
	Administrative review notification	N/A	10/07/15
	Donation(s) made to CPRIT/foundation	NO	10/07/15
	Assigned to primary reviewers	07/23/15	10/07/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/07/15
nd Assignment	Primary Reviewer 1 COI signed	07/17/15	10/07/15
	Primary Reviewer 2 COI signed	06/23/15	10/07/15
	Primary Reviewer 3 COI signed	06/23/15	10/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/07/15
	Primary Reviewer 1 critique submitted	08/11/15	10/07/15
	Primary Reviewer 2 critique submitted	08/09/15	10/07/15
		08/08/15	10/07/15
Budlada	Primary Reviewer 3 critique submitted Primary (Advocate) Reviewer 4 critique submitted	N/A	10/07/15
B. Preliminary Evaluation		Engelhard, Victor	10/07/15
evaluation	COI indicated by non-primary reviewer	08/17/15	10/07/15
	Preliminary Evaluation score summary sent to Chair	VES	
	Recommended for full review		10/07/15
	Applicant notified of outcome	09/01/15	10/07/15
	Assigned to primary reviewers	08/25/15	10/07/15
	Primary Reviewer 1 COI signed	07/17/15	10/07/15
	Primary Reviewer 2 COI signed	08/29/15	10/07/15
	Primary Reviewer 3 COI signed	06/23/15	10/07/15
	Primary (Advocate) Reviewer 4 COI signed	07/29/15	10/07/15
	Primary Reviewer 1 critique submitted	09/27/15	10/07/15
	Primary Reviewer 2 critique submitted	09/20/15	10/07/15
I. Peer Review	Primary Reviewer 3 critique submitted	09/17/15	10/07/15
Viceting	Primary (Advocate) Reviewer 4 critique submitted	09/14/15	10/07/15
viccung	COI indicated by non-primary reviewer	Engelhard, Victor	10/13/15
	COI recused from participation	YES	10/13/15
	Discussed at Peer Review Meeting	YES	10/07/15
	Peer Review Meeting	09/29/15	10/07/15
	Post review statements signed	10/12/15	10/13/15
	Third Party Observer Report	10/07/15	10/14/15
	Score report delivered to CSO	10/19/15	10/23/15
	Recommended for SRC Review	YES	10/07/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI Indicated by PIC member	NONE	11/03/15
	COI recused from participation	M. Kripke	11/03/15
i. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME OF NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO 11/19/15	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15 YES/NO	
	Award approved by Oversight Committee		
	Authority to advance funds requested	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160190 Individual Investigator Research Awards for Cancer in Children and Adolescents

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 45 applications for this RFA, including 1 that was later withdrawn. This application was assigned to the Clinical and Translational Cancer Research and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before me, the the day of November by WAYNE R. ROBERTS.	undersigned authority, on, 2015,
SanderRevel	
Notary Public, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY

2016

CYCLE

PROGRAM Research

AWARD MECHANISM

Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)

APPLICATION ID

RP160190

APPLICATION TITLE

Pediatric Radiation Oncology with Movie Induced Sedation Effect

(PROMISE)

APPLICANT NAME

Jiang, Steve

ORGANIZATION PANEL NAME

The University of Texas Southwestern Medical Center 16,1 Clinical / Translational Cancer Research (16.1 C/TCR)

Category	Compliance Requirement	Information	Attestation Do
	RFA published in Texas Register	02/27/15	10/07/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/07/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/07/15
man manadas	Date application submitted	05/19/15	10/07/15
l. Pre-Receipt	Method of submission	CARS	10/07/15
	Within receipt period	YES	10/07/15
	Appeal to submit application after CARS closed	N/A	10/07/15
	Appeal for late application submission accepted	N/A	10/07/15
	Administrative review notification	N/A	10/07/15
	Donation(s) made to CPRIT/foundation	NO	10/07/15
	Assigned to primary reviewers	N/A	10/07/15
. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/07/15
nd Assignment	Primary Reviewer 1 COI signed	N/A	10/07/15
	Primary Reviewer 2 COI signed	N/A	10/07/15
	Primary Reviewer 3 COI signed	N/A	10/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/07/15
	Primary Reviewer 1 critique submitted	N/A	10/07/15
	Primary Reviewer 2 critique submitted	N/A	10/07/15
	Primary Reviewer 3 critique submitted	N/A	10/07/15
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/07/15
valuation	COI indicated by non-primary reviewer	N/A	10/07/15
	Preliminary Evaluation score summary sent to Chair	N/A	10/07/15
	Recommended for full review	N/A	10/07/15
	Applicant notified of outcome	N/A	10/07/15
	Assigned to primary reviewers	08/25/15	10/07/15
	Primary Reviewer 1 COI signed	07/15/15	10/07/15
	Primary Reviewer 2 COI signed	06/23/15	10/07/15
	Primary Reviewer 3 COI signed	06/20/15	10/07/15
	Primary (Advocate) Reviewer 4 COI signed	08/27/15	10/07/15
	Primary Reviewer 1 critique submitted	09/22/15	10/07/15
	Primary Reviewer 2 critique submitted	09/11/15	10/07/15
	Primary Reviewer 3 critique submitted	09/20/15	10/07/15
l. Peer Review		09/04/15	10/07/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	NONE	10/07/15
	COI indicated by non-primary reviewer		
	COI recused from participation	N/A	10/13/15
	Discussed at Peer Review Meeting	YES	10/07/15
	Peer Review Meeting	09/29/15	10/07/15
	Post review statements signed	10/12/15	10/13/15
	Third Party Observer Report	10/07/15	10/14/15
	Score report delivered to CSO	10/19/15	10/23/15
	Recommended for SRC Review	YES	10/07/15
	COI Indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
. Final SRC	SRC Meeting	10/23/15	10/27/15
tecommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
. PIC Review	COI recused from participation	M. Kripke	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME OF NONE	
	COI recused from participation	YES/NO or N/A	4
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160192 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Basic Cancer Research Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 5th day of November , 2015, by WAYNE R. ROBERTS.

Sandra Reyes
Notary Public, State of Texas

Notary Public, State of Texas

My Commission Expires
SEPTEMBER 30, 2017

Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2016 **CYCLE** 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160192

APPLICATION TITLE Decoding Cellular Heterogeneity of Malignant Glioma

APPLICANT NAME Deneen, Benjamin
ORGANIZATION Baylor College of Medicine

PANEL NAME 16.1 Basic Cancer Research-1 (16.1 BCR-1)

Category	Compliance Requirement	laformation	Attestation Dat
	RFA published in Texas Register	02/27/15	10/11/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/11/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/11/15
	Date application submitted	05/12/15	10/11/15
1. Pre-Receipt	Method of submission	CARS	10/11/15
	Within receipt period	YES	10/11/15
	Appeal to submit application after CARS closed	N/A	10/11/15
	Appeal for late application submission accepted	N/A	10/11/15
	Administrative review notification	N/A	10/11/15
	Donation(s) made to CPRIT/foundation	NO	10/11/15
	Assigned to primary reviewers	07/17/15	10/11/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/11/15
and Assignment	Primary Reviewer 1 COI signed	06/24/15	10/11/15
	Primary Reviewer 2 COI signed	07/03/15	10/11/15
	Primary Reviewer 3 COI signed	07/04/15	10/11/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/11/15
	Primary Reviewer 1 critique submitted	07/26/15	10/11/15
	Primary Reviewer 2 critique submitted	08/05/15	10/11/15
	Primary Reviewer 3 critique submitted	08/04/15	10/11/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/11/15
Evaluation	COI indicated by non-primary reviewer	NONE	10/11/15
	Preliminary Evaluation score summary sent to Chair	08/06/15	10/11/15
	Recommended for full review	YES	10/11/15
	Applicant notified of outcome	09/01/15	10/11/15
	Assigned to primary reviewers	08/11/15	10/11/15
	Primary Reviewer 1 COI signed	06/24/15	10/11/15
	Primary Reviewer 2 COI signed	07/03/15	10/11/15
		07/04/15	10/11/15
	Primary Reviewer 3 COI signed Primary (Advocate) Reviewer 4 COI signed	06/15/15	10/11/15
		09/07/15	10/11/15
	Primary Reviewer 1 critique submitted Primary Reviewer 2 critique submitted	09/30/15	10/11/15
		09/23/15	10/11/15
4. Peer Review	Primary Reviewer 3 critique submitted	08/29/15	10/11/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	NONE	10/11/15
	COI indicated by non-primary reviewer	N/A	10/11/15
	COI recused from participation	YES	10/11/15
	Discussed at Peer Review Meeting		
	Peer Review Meeting	10/06/15	10/11/15
	Post review statements signed	10/12/15	10/14/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/11/15
	COI Indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
6. PIC Review	COI recused from participation	M. Kripke	11/03/15
o to iteriem	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	1
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	3
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	_
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160211 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications, for this RFA, including 5 that were later withdrawn. This application was assigned to the Basic Cancer Research Panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Moberts,

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ounty of Travis	
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WORN to and SUBSCRIBED before me, the	-
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otary Public, State of Texas	
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	SANDRA J. REYES Notary Public, State of Taxas
	Notary Public, State of Texas My Commission Expires
	SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160211

APPLICATION TITLE Novel Tumorigenic Mechanisms of the LKB1 Tumor Suppressor in Endometrial and Cervical Cancer

APPLICANT NAME Castrillon, Diego

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME 16.1 Basic Cancer Research-2 (16.1 BCR-2)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
	Date application submitted	05/19/15	10/09/15
. Pre-Receipt	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
2. Receipt, Referral, and Assignment	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	07/20/15	10/09/15
	Applicant notified of review panel assignment	06/30/15	10/09/15
	Primary Reviewer 1 COI signed	06/30/15	10/09/15
	Primary Reviewer 2 COI signed	07/08/15	10/09/15
	Primary Reviewer 3 COI signed	06/19/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	07/22/15	10/09/15
	Primary Reviewer 2 critique submitted	08/08/15	10/09/15
	Primary Reviewer 3 critique submitted	08/05/15	10/09/15
a nutturbu	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
I. Preliminary Evaluation	COI indicated by non-primary reviewer	NONE	10/09/15
Lvaidation	Preliminary Evaluation score summary sent to Chair	08/12/15	10/09/15
	Recommended for full review	YES	10/09/15
		09/01/15	10/09/15
	Applicant notified of outcome	08/21/15	10/09/15
	Assigned to primary reviewers	06/30/15	10/09/15
	Primary Reviewer 1 COI signed	07/08/15	10/09/15
	Primary Reviewer 2 COI signed	06/19/15	10/09/15
	Primary Reviewer 3 COI signed	08/06/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed		10/09/15
	Primary Reviewer 1 critique submitted	09/27/15	10/09/15
	Primary Reviewer 2 critique submitted	09/22/15	
1. Peer Review	Primary Reviewer 3 critique submitted	09/28/15	10/09/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/12/15	10/09/15
	COI indicated by non-primary reviewer	NONE	10/09/15
	COI recused from participation	N/A	10/09/15
	Discussed at Peer Review Meeting	YES	10/09/15
	Peer Review Meeting	10/05/15	10/09/15
	Post review statements signed	10/11/15	10/14/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/09/15
	COI Indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
5. PIC Review	COI recused from participation	M. Kripke	11/03/15
o. Pic Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
7. Oversight	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160229 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

State of Texas County of Travis	
	ED before me, the undersigned authority, on
the 5 th day of by WAYNE R. ROBERTS.	November , 2015,
$\alpha \Delta \Delta = -$	
Sandra Ikeyes	
Notary Public, State of Texa	S Victoria de la companya del companya de la companya del companya de la companya
	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160229

Imaging-based Quantitative Analysis of Vascular Perfusion

APPLICATION TITLE and Tissue Oxygenation to Improve Therapy of

Hepatocellular Carcinoma
APPLICANT NAME Avritscher, Rony

ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME 16.1 Imaging Technology and Informatics (16.1 ITI)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
	Date application submitted	05/18/15	10/09/15
1. Pre-Receipt	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	07/22/15	10/09/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
and Assignment	Primary Reviewer 1 COI signed	07/08/15	10/09/15
	Primary Reviewer 2 COI signed	07/10/15	10/09/15
	Primary Reviewer 3 COI signed	07/07/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	07/30/15	10/09/15
	Primary Reviewer 2 critique submitted	08/09/15	10/09/15
	Primary Reviewer 3 critique submitted	07/28/15	10/09/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
Evaluation	COI indicated by non-primary reviewer	NONE	10/09/15
	Preliminary Evaluation score summary sent to Chair	08/11/15	10/09/15
	Recommended for full review	YES	10/09/15
	Applicant notified of outcome	09/01/15	10/09/15
	Assigned to primary reviewers	08/17/15	10/09/15
	Primary Reviewer 1 COI signed	07/08/15	10/09/15
	Primary Reviewer 2 COI signed	07/10/15	10/09/15
	Primary Reviewer 3 COI signed	07/07/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	07/09/15	10/09/15
	Primary Reviewer 1 critique submitted	09/22/15	10/09/15
	Primary Reviewer 2 critique submitted	08/26/15	10/09/15
	Primary Reviewer 3 critique submitted	09/16/15	10/09/15
4. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	09/01/15	10/09/15
Meeting	COI indicated by non-primary reviewer	NONE	10/09/15
	COI recused from participation	N/A	10/09/15
	Discussed at Peer Review Meeting	YES	10/09/15
		10/01/15	10/09/15
	Peer Review Meeting	10/08/15	10/09/15
	Post review statements signed	10/08/15	10/14/15
	Third Party Observer Report	10/19/15	10/23/15
	Score report delivered to CSO Recommended for SRC Review	YES YES	10/09/15
	COI indicated by SRC member	NONE	10/28/15
		N/A	10/28/15
	COI recused from participation SRC Meeting	10/23/15	10/28/15
5. Final SRC Recommendation			10/28/15
Kecommendation	Third Party Observer Report	10/27/15	_
	Recommended for grant award	YES	10/28/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
6. PIC Review	COI recused from participation	M. Kripke	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	VES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	_
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160232 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Clinical and Translational Cancer Research and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Mayne R. Roberts,

State of Texas County of Travis	
SWORN to and SUBSCRIBED before the 5th day of November 1	
by WAYNE R. ROBERTS.	
Sandra Reyes	
Notary Public, State of Texas	
	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160232

APPLICATION TITLE

Understanding Biological and Physical Factors Affecting
Personne to Proton Thorapy to Improve its Clinical Effecting

Response to Proton Therapy to Improve its Clinical Effectiveness

APPLICANT NAME Mirkovic, Dragan

 ORGANIZATION
 The University of Texas M. D. Anderson Cancer Center

 PANEL NAME
 16.1 Clinical / Translational Cancer Research (16.1 C/TCR)

integory.	Compliance Requirement	Information	Attestation Da
	RFA published in Texas Register	02/27/15	10/07/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/07/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/07/15
	Date application submitted	05/20/15	10/07/15
1. Pre-Receipt	Method of submission	CARS	10/07/15
	Within receipt period	YES	10/07/15
	Appeal to submit application after CARS closed	N/A	10/07/15
	Appeal for late application submission accepted	N/A	10/07/15
	Administrative review notification	N/A	10/07/15
2. Receipt, Referral,	Donation(s) made to CPRIT/foundation	NO	10/07/15
	Assigned to primary reviewers	07/23/15	10/07/15
	Applicant notified of review panel assignment	06/30/15	10/07/15
	Primary Reviewer 1 COI signed	08/09/15	10/07/15
and Assignment	Primary Reviewer 2 COI signed	06/20/15	10/07/15
		07/17/15	10/07/15
	Primary Reviewer 3 COI signed	N/A	10/07/15
	Primary (Advocate) Reviewer 4 COI signed	08/12/15	10/07/15
	Primary Reviewer 1 critique submitted	08/01/15	10/07/15
	Primary Reviewer 2 critique submitted	08/01/15	10/07/15
	Primary Reviewer 3 critique submitted	N/A	10/07/15
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	NONE	10/07/15
valuation	COI indicated by non-primary reviewer		10/07/15
	Preliminary Evaluation score summary sent to Chair	08/17/15	10/07/15
	Recommended for full review	YES	_
	Applicant notified of outcome	09/01/15	10/07/15
	Assigned to primary reviewers	08/25/15	10/07/15
	Primary Reviewer 1 COI signed	08/09/15	10/07/15
	Primary Reviewer 2 COI signed	06/20/15	10/07/15
	Primary Reviewer 3 COI signed	07/17/15	10/07/15
	Primary (Advocate) Reviewer 4 COI signed	07/29/15	10/07/15
	Primary Reviewer 1 critique submitted	09/28/15	10/07/15
	Primary Reviewer 2 critique submitted	09/13/15	10/07/15
1. Peer Review	Primary Reviewer 3 critique submitted	09/27/15	10/07/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/14/15	10/07/15
wieering	COI indicated by non-primary reviewer	NONE	10/13/15
	COI recused from participation	N/A	10/13/15
	Discussed at Peer Review Meeting	YES	10/07/15
	Peer Review Meeting	09/29/15	10/07/15
	Post review statements signed	10/12/15	10/13/15
	Third Party Observer Report	10/07/15	10/14/15
	Score report delivered to CSO	10/19/15	10/23/15
	Recommended for SRC Review	YES	10/07/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation	M. Kripke	11/03/15
6. PIC Review	PIC review meeting	11/03/15	11/03/15
V.	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME OF NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight Committee Approval	Ponation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	11/18/15	
		YES/NO	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	TEO/ITO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160235 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Cancer Biology panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160235

APPLICATION TITLE Regulation of Tumor Aggressiveness and Immune

Suppression in Lung Adenocarcinoma

APPLICANT NAME Liu, Qingyun

ORGANIZATION The University of Texas Health Science Center at Houston

PANEL NAME 16.1 Cancer Biology (16.1 CB)

Category	Compliance Requirement.	Information	Artestation Date
	RFA published in Texas Register	02/27/15	10/12/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/12/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/12/15
L. Pre-Receipt	Date application submitted	05/20/15	10/12/15
1. Pre-Receipt	Method of submission	CARS	10/12/15
	Within receipt period	YES	10/12/15
	Appeal to submit application after CARS closed	N/A	10/12/15
	Appeal for late application submission accepted	N/A	10/12/15
	Administrative review notification	N/A	10/12/15
	Donation(s) made to CPRIT/foundation	NO	10/12/15
	Assigned to primary reviewers	07/20/15	10/12/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/12/15
and Assignment	Primary Reviewer 1 COI signed	06/23/15	10/12/15
	Primary Reviewer 2 COI signed	07/08/15	10/12/15
	Primary Reviewer 3 COI signed	07/06/15	10/12/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/12/15
	Primary Reviewer 1 critique submitted	07/29/15	10/12/15
	Primary Reviewer 2 critique submitted	08/07/15	10/12/15
	Primary Reviewer 3 critique submitted	08/04/15	10/12/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/12/15
Evaluation	COI indicated by non-primary reviewer	NONE	10/12/15
	Preliminary Evaluation score summary sent to Chair	08/10/15	10/12/15
	Recommended for full review	YES	10/12/15
	Applicant notified of outcome	09/01/15	10/12/15
	Assigned to primary reviewers	08/18/15	10/12/15
	Primary Reviewer 1 COI signed	06/23/15	10/12/15
	Primary Reviewer 2 COI signed	07/08/15	10/12/15
	Primary Reviewer 3 COI signed	07/06/15	10/12/15
	Primary (Advocate) Reviewer 4 COI signed	06/19/15	10/12/15
	Primary (Advocate) Reviewer 4 Col signed Primary Reviewer 1 critique submitted	09/30/15	10/12/15
	Primary Reviewer 2 critique submitted	09/29/15	10/12/15
		09/30/15	10/12/15
1. Peer Review	Primary Reviewer 3 critique submitted	_	_
Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/16/15 NONE	10/12/15
	COI indicated by non-primary reviewer		10/12/15
	COI recused from participation	N/A	10/12/15
	Discussed at Peer Review Meeting	YES	10/12/15
	Peer Review Meeting	10/07/15	10/12/15
	Post review statements signed	10/15/15	10/22/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/12/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
6. PIC Review	COI recused from participation	M. Kripke	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	-11

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

The identity of the attesting party is retained by CPRIT.



CEO AFFIDAVIT Application RP160237 Individual Investigator Research Awards for Cancer in Children and Adolescents

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 45 applications for this RFA, including 1 that was later withdrawn. This application was assigned to the Cancer Biology panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)

APPLICATION ID RP160237

A POVEL Epigenetic Reader as TherapeuticTtarget in MLL-

Translocated Pediatric Leukemias

APPLICANT NAME Shi, Xiaobing

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME 16,1 Cancer Biology (16.1 CB)

Category	Compliance Requirement	Information	Attestation Dat
	RFA published in Texas Register	02/27/15	10/12/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/12/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/12/15
I Dec Decelet	Date application submitted	05/18/15	10/12/15
1. Pre-Receipt	Method of submission	CARS	10/12/15
	Within receipt period	YES	10/12/15
	Appeal to submit application after CARS closed	N/A	10/12/15
	Appeal for late application submission accepted	N/A	10/12/15
	Administrative review notification	N/A	10/12/15
	Donation(s) made to CPRIT/foundation	NO	10/12/15
	Assigned to primary reviewers	N/A	10/12/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/12/15
and Assignment	Primary Reviewer 1 COI signed	N/A	10/12/15
	Primary Reviewer 2 COI signed	N/A	10/12/15
	Primary Reviewer 3 COI signed	N/A	10/12/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/12/15
	Primary Reviewer 1 critique submitted	N/A	10/12/15
	Primary Reviewer 2 critique submitted	N/A	10/12/15
	Primary Reviewer 3 critique submitted	N/A	10/12/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/12/15
Evaluation	COI indicated by non-primary reviewer	N/A	10/12/15
	Preliminary Evaluation score summary sent to Chair	N/A	10/12/15
	Recommended for full review	N/A	10/12/15
	Applicant notified of outcome	N/A	10/12/15
	Assigned to primary reviewers	08/18/15	10/12/15
	Primary Reviewer 1 COI signed	06/18/15	10/12/15
	Primary Reviewer 2 COI signed	06/18/15	10/12/15
	Primary Reviewer 3 COI signed	07/03/15	10/12/15
	Primary (Advocate) Reviewer 4 COI signed	06/19/15	10/12/15
	Primary Reviewer 1 critique submitted	09/15/15	10/12/15
	Primary Reviewer 2 critique submitted	09/24/15	10/12/15
A Door Dovinu	Primary Reviewer 3 critique submitted	09/30/15	10/12/15
4. Peer Review Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/17/15	10/12/15
inceting.	COI indicated by non-primary reviewer	NONE	10/12/15
	COI recused from participation	N/A	10/12/15
	Discussed at Peer Review Meeting	YES	10/12/15
	Peer Review Meeting	10/07/15	10/12/15
	Post review statements signed	10/15/15	10/22/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/12/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI Indicated by PIC member	NONE	11/03/15
5. PIC Review	COI recused from participation	M. Kripke	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

The identity of the attesting party is retained by CPRIT.



CEO AFFIDAVIT Application RP160242 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications, for this RFA, including 5 that were later withdrawn. This application was assigned to the Basic Cancer Research Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

 A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas	
County of Travis	
SWORN to and SUBSCRIBED before me, the the day of November	e undersigned authority, on, 2015,
by WAYNE R. ROBERTS.	
Sandra Reyes Notary Public, State of Texas	
Notary Fublic, State of Texas	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Borid

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2016 CYCLE 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160242

APPLICATION TITLE Mechanisms and Targeting Strategies for SWI/SNF

Mutations in Cancer

APPLICANT NAME Shen, Xuetong

ORGANIZATION The University

The University of Texas M. D. Anderson Cancer Center

PANEL NAME 16.1 Basic Cancer Research-1 (16.1 BCR-1)

Category	Compliance Requirement	Information	Attestation Da
	RFA published in Texas Register	02/27/15	10/11/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/11/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/11/15
	Date application submitted	05/19/15	10/11/15
. Pre-Receipt	Method of submission	CARS	10/11/15
	Within receipt period	YES	10/11/15
	Appeal to submit application after CARS closed	N/A	10/11/15
	Appeal for late application submission accepted	N/A	10/11/15
	Administrative review notification	N/A	10/11/15
	Donation(s) made to CPRIT/foundation	NO	10/11/15
	Assigned to primary reviewers	07/17/15	10/11/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/11/15
and Assignment	Primary Reviewer 1 COI signed	06/18/15	10/11/15
	Primary Reviewer 2 COI signed	06/24/15	10/11/15
	Primary Reviewer 3 COI signed	06/30/15	10/11/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/11/15
	Primary Reviewer 1 critique submitted	08/06/15	10/11/15
	Primary Reviewer 2 critique submitted	07/26/15	10/11/15
	Primary Reviewer 3 critique submitted	07/20/15	10/11/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/11/15
Evaluation	COI indicated by non-primary reviewer	NONE	10/11/15
Lvaluation	Preliminary Evaluation score summary sent to Chair	08/06/15	10/11/15
	Recommended for full review	YES	10/11/15
	Applicant notified of outcome	09/01/15	10/11/15
	Assigned to primary reviewers	08/11/15	10/11/15
	Primary Reviewer 1 COI signed	06/18/15	10/11/15
	Primary Reviewer 2 COI signed	06/24/15	10/11/15
	Primary Reviewer 3 COI signed	06/30/15	10/11/15
		06/18/15	10/11/15
	Primary (Advocate) Reviewer 4 COI signed Primary Reviewer 1 critique submitted	09/30/15	10/11/15
		08/25/15	10/11/15
	Primary Reviewer 2 critique submitted	08/20/15	10/11/15
4. Peer Review	Primary Reviewer 3 critique submitted	09/01/15	10/11/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	NONE	10/11/15
	COI indicated by non-primary reviewer		10/11/15
	COI recused from participation	N/A YES	10/11/15
	Discussed at Peer Review Meeting		10/11/15
	Peer Review Meeting	10/06/15	10/11/15
	Post review statements signed	10/12/15	10/14/15
	Third Party Observer Report	10/13/15	
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/11/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
6. PIC Review	COI recused from participation	M. Kripke	11/03/15
b. I le neview	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	-
Committee Approval	Presented to CPRIT Oversight Committee	10/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



CEO AFFIDAVIT Application RP160249 Individual Investigator Research Awards for Cancer in Children and Adolescents

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 45 applications for this RFA, including 1 that was later withdrawn. This application was assigned to the Basic Cancer Research Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on

the 5th day of

November

by WAYNE R. ROBERTS.

Sandra Reyes

Notary Public, State of Texas

SANDRA J. REYES

Notary Public, State of Texas
My Commission Expires
SEPTEMBER 30, 2017

, 2015,

Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards for Cancer in

Children and Adolescents (IIRACCA)

APPLICATION ID RP160249

APPLICATION TITLE DIS3L2 in Childhood Wilms Tumor: Mechanism to

Medicines

APPLICANT NAME Mendell, Joshua

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME 16,1 Basic Cancer Research-1 (16.1 BCR-1)

Category	Compliance Requirement	Information	Attestation De
	RFA published in Texas Register	02/27/15	10/11/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/11/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/11/15
	Date application submitted	05/19/15	10/11/15
1. Pre-Receipt	Method of submission	CARS	10/11/15
	Within receipt period	YES	10/11/15
	Appeal to submit application after CARS closed	N/A	10/11/15
	Appeal for late application submission accepted	N/A	10/11/15
	Administrative review notification	N/A	10/11/15
	Donation(s) made to CPRIT/foundation	NO	10/11/15
	Assigned to primary reviewers	N/A	10/11/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/11/15
and Assignment	Primary Reviewer 1 COI signed	N/A	10/11/15
· ·	Primary Reviewer 2 COI signed	N/A	10/11/15
	Primary Reviewer 3 COI signed	N/A	10/11/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/11/15
	Primary Reviewer 1 critique submitted	N/A	10/11/15
	Primary Reviewer 2 critique submitted	N/A	10/11/15
	Primary Reviewer 3 critique submitted	N/A	10/11/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/11/15
S. Preliminary Evaluation	COI indicated by non-primary reviewer	N/A	10/11/15
	Preliminary Evaluation score summary sent to Chair	N/A	10/11/15
	Recommended for full review	N/A	10/11/15
	Applicant notified of outcome	N/A	10/11/15
		08/11/15	10/11/15
	Assigned to primary reviewers	07/02/15	_
	Primary Reviewer 1 COI signed	07/16/15	10/11/15
	Primary Reviewer 2 COI signed		
	Primary Reviewer 3 COI signed	07/03/15	10/11/15
	Primary (Advocate) Reviewer 4 COI signed	06/18/15	10/11/15
	Primary Reviewer 1 critique submitted	09/10/15	10/11/15
	Primary Reviewer 2 critique submitted	09/09/15	10/11/15
4. Peer Review	Primary Reviewer 3 critique submitted	09/30/15	10/11/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/02/15	10/11/15
	COI indicated by non-primary reviewer	NONE	10/11/15
	COI recused from participation	N/A	10/11/15
	Discussed at Peer Review Meeting	YES	10/11/15
	Peer Review Meeting	10/06/15	10/11/15
	Post review statements signed	10/12/15	10/14/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/11/15
	COI Indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI Indicated by PIC member	NONE	11/03/15
5. PIC Review	COI recused from participation	M. Kripke	11/03/15
o. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO of N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

The identity of the attesting party is retained by CPRIT.



CEO AFFIDAVIT Application RP160255 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Basic Cancer Research Panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

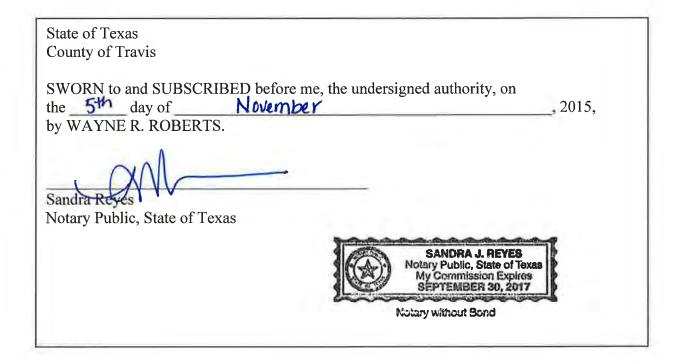
In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas



 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160255

APPLICATION TITLE Structural and Functional Analyses of the Spindle

APPLICANT NAME Luo, Xuelian

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME 16.1 Basic Cancer Research-2 (16,1 BCR-2)

Category	Compliance Requirement	information	Attestation Dat
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
	Date application submitted	05/19/15	10/09/15
1. Pre-Receipt	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	07/20/15	10/09/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
and Assignment	Primary Reviewer 1 COI signed	06/26/15	10/09/15
	Primary Reviewer 2 COI signed	06/19/15	10/09/15
	Primary Reviewer 3 COI signed	07/02/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	07/27/15	10/09/15
	Primary Reviewer 2 critique submitted	08/05/15	10/09/15
	Primary Reviewer 3 critique submitted	07/29/15	10/09/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
Evaluation	COI indicated by non-primary reviewer	NONE	10/09/15
	Preliminary Evaluation score summary sent to Chair	08/12/15	10/09/15
	Recommended for full review	YES YES	10/09/15
	Applicant notified of outcome	09/01/15	10/09/15
	Assigned to primary reviewers	08/21/15	10/09/15
		06/26/15	_
	Primary Reviewer 1 COI signed		10/09/15
	Primary Reviewer 2 COI signed	06/19/15	10/09/15
	Primary Reviewer 3 COI signed Primary (Advocate) Reviewer 4 COI signed	07/02/15	10/09/15
		08/27/15	10/09/15
	Primary Reviewer 1 critique submitted	09/11/15	10/09/15
	Primary Reviewer 2 critique submitted	09/28/15	10/09/15
1. Peer Review	Primary Reviewer 3 critique submitted	09/21/15	10/09/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/28/15	10/09/15
	COI indicated by non-primary reviewer	NONE	10/09/15
	COI recused from participation	N/A	10/09/15
	Discussed at Peer Review Meeting	YES	10/09/15
	Peer Review Meeting	10/05/15	10/09/15
	Post review statements signed	10/11/15	10/14/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/09/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
. Final SRC	SRC Meeting	10/23/15	10/27/15
lecommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
. PIC Review	COI recused from participation	M. Kripke	11/03/15
ar ic nevicu	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications,

The identity of the attesting party is retained by CPRIT.



CEO AFFIDAVIT Application RP160268 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Basic Cancer Research Panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

2016 FΥ CYCLE PROGRAM

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160268

DNA Damage-Induced Small Non-Coding RNAs: Mechanism APPLICATION TITLE

and Their Role in Cancer Development

APPLICANT NAME

The University of Texas Southwestern Medical Center ORGANIZATION

16.1 Basic Cancer Research-2 (16,1 BCR-2) PANEL NAME

sategory	Compliance Requirement	Information.	Attestation Da
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
	Date application submitted	05/20/15	10/09/15
. Pre-Receipt	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	07/20/15	10/09/15
. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
nd Assignment	Primary Reviewer 1 COI signed	07/14/15	10/09/15
	Primary Reviewer 2 COI signed	06/19/15	10/09/15
	Primary Reviewer 3 COI signed	07/08/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	08/12/15	10/09/15
	Primary Reviewer 2 critique submitted	08/07/15	10/09/15
	Primary Reviewer 3 critique submitted	08/07/15	10/09/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
valuation	COI indicated by non-primary reviewer	NONE	10/09/15
.valuation	Preliminary Evaluation score summary sent to Chair	08/12/15	10/09/15
	Recommended for full review	YES	10/09/15
	Applicant notified of outcome	09/01/15	10/09/15
	Assigned to primary reviewers	08/21/15	10/09/15
		09/10/15	10/09/15
	Primary Reviewer 1 COI signed	06/20/15	10/09/15
	Primary Reviewer 2 COI signed	06/19/15	10/09/15
	Primary Reviewer 3 COI signed	08/06/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	09/30/15	10/09/15
	Primary Reviewer 1 critique submitted	09/30/15	10/09/15
	Primary Reviewer 2 critique submitted		10/09/15
1. Peer Review	Primary Reviewer 3 critique submitted	09/26/15	10/09/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/12/15	10/09/15
	COI indicated by non-primary reviewer	NONE	
	COI recused from participation	N/A	10/09/15
	Discussed at Peer Review Meeting	YES	10/09/15
	Peer Review Meeting	10/05/15	10/09/15
	Post review statements signed	10/11/15	10/14/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/09/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
5. PIC Review	COI recused from participation	M. Krlpke	11/03/15
b. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME OF NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

The identity of the attesting party is retained by CPRIT.



CEO AFFIDAVIT Application RP160283 Research Training Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Research Training Awards* Request for Applications (RFA). CPRIT received 13 applications for this RFA. This application was assigned to the Basic Cancer Research Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on

November

the 5th day of ____

_, 2015,

by WAYNE R. ROBERTS.

Sandra Reyes

Notary Public, State of Texas



Notary without Bond

CYCLE PROGRAM 1

Research

AWARD MECHANISM Research Training Awards (RTA)

APPLICATION ID

RP160283

Baylor College of Medicine Comprehensive Cancer Training

APPLICATION TITLE

Program

APPLICANT NAME

Rosen, Jeffrey

ORGANIZATION

Baylor College of Medicine

PANEL NAME

16.1 Basic Cancer Research-1 (16.1 BCR-1)

Citesory	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	02/27/15	10/11/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/11/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/11/15
1. Pre-Receipt	Date application submitted	05/08/15	10/11/15
1. Pre-Receipt	Method of submission	CARS	10/11/15
	Within receipt period	YES	10/11/15
	Appeal to submit application after CARS closed	N/A	10/11/15
	Appeal for late application submission accepted	N/A	10/11/15
	Administrative review notification	N/A	10/11/15
	Donation(s) made to CPRIT/foundation	NO	10/11/15
	Assigned to primary reviewers	N/A	10/11/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/11/15
and Assignment	Primary Reviewer 1 COI signed	N/A	10/11/15
	Primary Reviewer 2 COI signed	N/A	10/11/15
	Primary Reviewer 3 COI signed	N/A	10/11/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/11/15
	Primary Reviewer 1 critique submitted	N/A	10/11/15
	Primary Reviewer 2 critique submitted	N/A	10/11/15
	Primary Reviewer 3 critique submitted	N/A	10/11/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/11/15
Evaluation	COI indicated by non-primary reviewer	N/A	10/11/15
	Preliminary Evaluation score summary sent to Chair	N/A	10/11/15
	Recommended for full review	N/A	10/11/15
	Applicant notified of outcome	N/A	10/11/15
	Assigned to primary reviewers	08/11/15	10/11/15
	Primary Reviewer 1 COI signed	06/18/15	10/11/15
	Primary Reviewer 2 COI signed	07/02/15	10/11/15
	Primary Reviewer 3 COI signed	06/30/15	10/11/15
	Primary (Advocate) Reviewer 4 COI signed	06/18/15	10/11/15
	Primary Reviewer 1 critique submitted	09/22/15	10/11/15
	Primary Reviewer 2 critique submitted	09/02/15	10/11/15
4 December	Primary Reviewer 3 critique submitted	09/18/15	10/11/15
4. Peer Review Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/07/15	10/11/15
wieeting	COI indicated by non-primary reviewer	NONE	10/11/15
	COI recused from participation	N/A	10/11/15
	Discussed at Peer Review Meeting	YES	10/11/15
	Peer Review Meeting	10/06/15	10/11/15
	Post review statements signed	10/12/15	10/14/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/11/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
5. PIC Review	COI recused from participation	N/A	11/03/15
o. Pic Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	A



CEO AFFIDAVIT Application RP160307 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Cancer Biology panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R/Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis		
SWORN to and SUBSCRIBED b	efore me, the undersigned authority, on	, 2015,
the 5th day of N by WAYNE R. ROBERTS.	DYRITADRY	, 2015,
Sandra Reyes		
Notary Public, State of Texas	TANDER I PRICE	TI.
	Matery Public, State of Texas My Cornmission Expires MPTEMBER 30, 2017	s
	Natary without Bond	

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160307

APPLICATION TITLE Targeting Metastatic Pathways

APPLICANT NAME Terada, Lance

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME 16.1 Cancer Biology (16.1 CB)

Category	Compliance Requirement	Information	Attestation Dat
	RFA published in Texas Register	02/27/15	10/12/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/12/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/12/15
	Date application submitted	05/19/15	10/12/15
l. Pre-Receipt	Method of submission	CARS	10/12/15
	Within receipt period	YES	10/12/15
	Appeal to submit application after CARS closed	N/A	10/12/15
	Appeal for late application submission accepted	N/A	10/12/15
	Administrative review notification	N/A	10/12/15
	Donation(s) made to CPRIT/foundation	NO	10/12/15
	Assigned to primary reviewers	07/20/15	10/12/15
. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/12/15
nd Assignment	Primary Reviewer 1 COI signed	06/27/15	10/12/15
	Primary Reviewer 2 COI signed	07/03/15	10/12/15
	Primary Reviewer 3 COI signed	07/06/15	10/12/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/12/15
	Primary Reviewer 1 critique submitted	08/04/15	10/12/15
	Primary Reviewer 2 critique submitted	08/06/15	10/12/15
	Primary Reviewer 3 critique submitted	08/04/15	10/12/15
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/12/15
valuation	COI indicated by non-primary reviewer	NONE	10/12/15
	Preliminary Evaluation score summary sent to Chair	08/10/15	10/12/15
	Recommended for full review	YES	10/12/15
	Applicant notified of outcome	09/01/15	10/12/15
	Assigned to primary reviewers	08/18/15	10/12/15
	Primary Reviewer 1 COI signed	07/06/15	10/12/15
	Primary Reviewer 2 COI signed	06/23/15	10/12/15
	Primary Reviewer 3 COI signed	07/06/15	10/12/15
	Primary (Advocate) Reviewer 4 COI signed	08/13/15	10/12/15
	Primary Reviewer 1 critique submitted	09/19/15	10/12/15
	Primary Reviewer 2 critique submitted	09/29/15	10/12/15
	Primary Reviewer 3 critique submitted	09/16/15	10/12/15
4. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	09/01/15	10/12/15
Meeting	COI indicated by non-primary reviewer	NONE	10/12/15
	COI recused from participation	N/A	10/12/15
	Discussed at Peer Review Meeting	YES	10/12/15
	Peer Review Meeting	10/07/15	10/12/15
	Post review statements signed	10/15/15	10/22/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/12/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation	M. Kripke	11/03/15
5. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

The identity of the attesting party is retained by CPRIT.



CEO AFFIDAVIT Application RP160318 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications, for this RFA, including 5 that were later withdrawn. This application was assigned to the Basic Cancer Research Panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FΥ 2016 CYCLE PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160318

Role of Long Non-Coding RNAs in Breast Cancer: APPLICATION TITLE Identification, Characterization, and Determination of

Molecular Functions APPLICANT NAME

Kraus, W. Lee

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME 16.1 Basic Cancer Research-2 (16.1 BCR-2)

Category	Compliance Requirement	Information	Attestation De
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
	Date application submitted	05/19/15	10/09/15
L. Pre-Receipt	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	N/A	10/09/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
and Assignment	Primary Reviewer 1 COI signed	N/A	10/09/15
and Assignment	Primary Reviewer 2 COI signed	N/A	10/09/15
		N/A	10/09/15
	Primary Reviewer 3 COI signed	N/A	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted		10/09/15
	Primary Reviewer 2 critique submitted	N/A	_
	Primary Reviewer 3 critique submitted	N/A	10/09/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
Evaluation	COI indicated by non-primary reviewer	N/A	10/09/15
	Preliminary Evaluation score summary sent to Chair	N/A	10/09/15
	Recommended for full review	N/A	10/09/15
	Applicant notified of outcome	N/A	10/09/15
	Assigned to primary reviewers	08/21/15	10/09/15
	Primary Reviewer 1 COI signed	06/25/15	10/09/15
	Primary Reviewer 2 COI signed	07/27/15	10/09/15
	Primary Reviewer 3 COI signed	06/19/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	08/27/15	10/09/15
	Primary Reviewer 1 critique submitted	09/27/15	10/09/15
	Primary Reviewer 2 critique submitted	09/28/15	10/09/15
4. Peer Review	Primary Reviewer 3 critique submitted	09/26/15	10/09/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/28/15	10/09/15
	COI indicated by non-primary reviewer	NONE	10/09/15
	COI recused from participation	N/A	10/09/15
	Discussed at Peer Review Meeting	YES	10/09/15
	Peer Review Meeting	10/05/15	10/09/15
	Post review statements signed	10/11/15	10/14/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/09/15
	COI Indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation	M. Kripke	11/03/15
5. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Inditionity to advance raines requested	, 20,110	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CEO AFFIDAVIT Application RP160319 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were withdrawn. This application was assigned to the Basic Cancer Research Panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

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Mark	210
Wayne R. Ro	berts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas	
County of Travis	
SWORN to and SUBSCRIBED before me, the under the	ersigned authority, on, 2015,
OY WATNER, ROBERTS.	
Sandra Reyes Notary Public, State of Texas	
Notary Fublic, State of Texas	SANDRA J. REYES
	Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

2016

CYCLE PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID

Role of PARP-1 in Estrogen Receptor Enhancer Function APPLICATION TITLE

and Gene Regulation Outcomes in Breast Cancers

APPLICANT NAME

ORGANIZATION

The University of Texas Southwestern Medical Center

16.1 Basic Cancer Research-2 (16.1 BCR-2) PANEL NAME

ategory.	Compliance dequirement	Information	Attestation Dat
	RFA published in Texas Register	02/27/15	110/9/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	110/9/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	110/9/15
	Date application submitted	05/19/15	110/9/15
. Pre-Receipt	Method of submission	CARS	110/9/15
	Within receipt period	YES	110/9/15
	Appeal to submit application after CARS closed	N/A:	110/9/15
	Appeal for late application submission accepted	N/A	110/9/15
	Administrative review notification	N/A	110/9/15
	Donation(s) made to CPRIT/foundation	NO	110/9/15
	Assigned to primary reviewers	07/20/15	110/9/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	110/9/15
and Assignment	Primary Reviewer 1 COI signed	07/02/15	110/9/15
and 7 dangininone	Primary Reviewer 2 COI signed	06/25/15	110/9/15
	Primary Reviewer 3 COI signed	06/19/15	110/9/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	110/9/15
	Primary Reviewer 1 critique submitted	08/06/15	110/9/15
	Primary Reviewer 2 critique submitted	07/27/15	110/9/15
	Primary Reviewer 3 critique submitted	08/07/15	110/9/15
3 Declimina -	Primary (Advocate) Reviewer 4 critique submitted	N/A	110/9/15
3. Preliminary Evaluation	COI indicated by non-primary reviewer	NONE	110/9/15
Evaluation	Preliminary Evaluation score summary sent to Chair	08/12/15	110/9/15
	Recommended for full review	YES	110/9/15
		09/01/15	110/9/15
	Applicant notified of outcome	08/21/15	110/9/15
	Assigned to primary reviewers	07/02/15	110/9/15
	Primary Reviewer 1 COI signed Primary Reviewer 2 COI signed	06/25/15	110/9/15
		06/19/15	110/9/15
	Primary Reviewer 3 COI signed	08/06/15	110/9/15
	Primary (Advocate) Reviewer 4 COI signed	09/21/15	110/9/15
	Primary Reviewer 1 critique submitted	09/27/15	110/9/15
	Primary Reviewer 2 critique submitted	09/26/15	110/9/15
4. Peer Review	Primary Reviewer 3 critique submitted	09/12/15	110/9/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	NONE	110/9/15
	COI indicated by non-primary reviewer	N/A	110/9/15
	COI recused from participation	YES	110/9/15
	Discussed at Peer Review Meeting	10/05/15	110/9/15
	Peer Review Meeting	10/03/13	10/14/15
	Post review statements signed	10/11/15	10/14/15
	Third Party Observer Report	10/19/15	10/22/15
	Score report delivered to CSO	YES	10/09/15
	Recommended for SRC Review		10/27/15
	COI indicated by SRC member	NONE N/A	10/27/15
	COI recused from participation		10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/28/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
6. PIC Review	COI recused from participation	M. Kripke	11/03/15
D. FIC REVIEW	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	GEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME OF NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to edvance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160340 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Basic Cancer Research Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160340

APPLICATION TITLE
The Role of the Lats Kinases in Sarcomatoid Renal Cell

Carcinoma

APPLICANT NAME Carroll, Thomas

ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME 16,1 Basic Cancer Research-1 (16.1 BCR-1)

Category	Compliance Requirement	Information	Attestation Dat
	RFA published in Texas Register	02/27/15	10/11/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/11/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/11/15
	Date application submitted	05/20/15	10/11/15
L. Pre-Receipt	Method of submission	CARS	10/11/15
	Within receipt period	YES	10/11/15
	Appeal to submit application after CARS closed	N/A	10/11/15
	Appeal for late application submission accepted	N/A	10/11/15
	Administrative review notification	N/A	10/11/15
	Donation(s) made to CPRIT/foundation	NO	10/11/15
	Assigned to primary reviewers	07/17/15	10/11/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/11/15
and Assignment	Primary Reviewer 1 COI signed	06/18/15	10/11/15
and resignment	Primary Reviewer 2 COI signed	06/25/15	10/11/15
	Primary Reviewer 3 COI signed	06/24/15	10/11/15
		N/A	10/11/15
	Primary (Advocate) Reviewer 4 COI signed Primary Reviewer 1 critique submitted	08/06/15	10/11/15
	Primary Reviewer 2 critique submitted	07/17/15	10/11/15
	Primary Reviewer 3 critique submitted	07/18/15	10/11/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/11/15
Evaluation	COI indicated by non-primary reviewer	NONE	10/11/15
	Preliminary Evaluation score summary sent to Chair	08/06/15	10/11/15
	Recommended for full review	YES	10/11/15
	Applicant notified of outcome	09/01/15	10/11/15
	Assigned to primary reviewers	08/11/15	10/11/15
	Primary Reviewer 1 COI signed	06/18/15	10/11/15
	Primary Reviewer 2 COI signed	06/25/15	10/11/15
	Primary Reviewer 3 COI signed	06/24/15	10/11/15
	Primary (Advocate) Reviewer 4 COI signed	06/15/15	10/11/15
	Primary Reviewer 1 critique submitted	10/04/15	10/11/15
	Primary Reviewer 2 critique submitted	08/17/15	10/11/15
4. Peer Review	Primary Reviewer 3 critique submitted	09/28/15	10/11/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/13/15	10/11/15
meeting.	COI indicated by non-primary reviewer	NONE	10/11/15
	COI recused from participation	N/A	10/11/15
	Discussed at Peer Review Meeting	YES	10/11/15
	Peer Review Meeting	10/06/15	10/11/15
	Post review statements signed	10/12/15	10/14/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/11/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation	M. Kripke	11/03/15
5. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	22, 33, 13
	COI indicated by Oversight Committee	NAME or NONE	
		YES/NO or N/A	
1 Constable	COI recused from participation		
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160345 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Clinical and Translational Cancer Research and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas	
County of Travis	
	a 1 1 1 1 1 5
SWORN to and SUBSCRIBED before me,	the undersigned authority, on
the 5th day of Novembe	Y , 2015,
by WAYNE R. ROBERTS.	
~ 0	
Sandra Reves	
Notary Public, State of Texas	
Notary 1 dolle, State of Texas	Contraction of the Contraction o
	SANDRA J. REYES
	Notary Public, State of Texas
	My Commission Expires SEPTEMBER 30, 2017
	Graffie Contraction Charles Contraction Contractions
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

2016 FY CYCLE PROGRAM

Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

RP160345 APPLICATION ID

Engineering T Cells to Ensure Specificity for Tumor Cells and Their APPLICATION TITLE

Environment Arber, Caroline

APPLICANT NAME Baylor College of Medicine ORGANIZATION

16.1 Clinical / Translational Cancer Research (16.1 C/TCR) PANEL NAME

Category	Compliance Requirement	Information	Attestation Dal
	RFA published in Texas Register	02/27/15	10/07/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/07/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/07/15
	Date application submitted	05/18/15	10/07/15
. Pre-Receipt	Method of submission	CARS	10/07/15
	Within receipt period	YES	10/07/15
	Appeal to submit application after CARS closed	N/A	10/07/15
	Appeal for late application submission accepted	N/A	10/07/15
	Administrative review notification	N/A	10/07/15
	Donation(s) made to CPRIT/foundation	NO	10/07/15
	Assigned to primary reviewers	07/23/15	10/07/15
. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/07/15
nd Assignment	Primary Reviewer 1 COI signed	06/23/15	10/07/15
	Primary Reviewer 2 COI signed	07/14/15	10/07/15
	Primary Reviewer 3 COI signed	06/26/15	10/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/07/15
	Primary Reviewer 1 critique submitted	08/11/15	10/07/15
	Primary Reviewer 2 critique submitted	08/11/15	10/07/15
	Primary Reviewer 3 critique submitted	08/13/15	10/07/15
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/07/15
valuation	COI indicated by non-primary reviewer	NONE	10/07/15
	Preliminary Evaluation score summary sent to Chair	08/17/15	10/07/15
	Recommended for full review	YES	10/07/15
	Applicant notified of outcome	09/01/15	10/07/15
	Assigned to primary reviewers	08/25/15	10/07/15
	Primary Reviewer 1 COI signed	06/23/15	10/07/15
	Primary Reviewer 2 COI signed	08/26/15	10/07/15
	Primary Reviewer 3 COI signed	06/26/15	10/07/15
	Primary (Advocate) Reviewer 4 COI signed	08/27/15	10/07/15
	Primary Reviewer 1 critique submitted	09/28/15	10/07/15
	Primary Reviewer 2 critique submitted	09/19/15	10/07/15
	Primary Reviewer 3 critique submitted	09/22/15	10/07/15
. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	09/09/15	10/07/15
Meeting	COI indicated by non-primary reviewer	NONE	10/13/15
	COI recused from participation	N/A	10/13/15
	Discussed at Peer Review Meeting	YES	10/07/15
	Peer Review Meeting	09/29/15	10/07/15
	Post review statements signed	10/12/15	10/13/15
	Third Party Observer Report	10/07/15	10/14/15
	Score report delivered to CSO	10/19/15	10/23/15
	Recommended for SRC Review	YES	10/07/15
_	COI Indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
r rilene	SRC Meeting	10/23/15	10/27/15
5. Final SRC Recommendation		10/27/15	10/28/15
Recommendation	Third Party Observer Report Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
	10	M. Kripke	11/03/15
5. PIC Review	COI recused from participation	11/03/15	11/03/15
	PiC review meeting.	YES YES	11/03/15
	Recommended for grant award	DATE	22,00/10
	CEO Notification to Oversight Committee	NAME OF NONE	
	COI indicated by Oversight Committee member	VES/NO dr N/A	
	COI recused from participation		
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160384 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Clinical and Translational Cancer Research and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis	
	1 1 1 1 1 1 1
SWORN to and SUBSCRIBED before me, the but day of November	ne undersigned authority, on , 2015,
by WAYNE R. ROBERTS.	
Sandra Reyes Notary Public, State of Texas	_
Notary Fublic, State of Texas	-
	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

CYCLE 1 PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160384

Promoting The Functions of Memory T cells for Adoptive T Cell APPLICATION TITLE

Therapy Wang, Jin

APPLICANT NAME Baylor College of Medicine ORGANIZATION

PANEL NAME 16.1 Clinical / Translational Cancer Research (16.1 C/TCR)

Category	Compliance Requirement	Information	Attestation Dat
	RFA published in Texas Register	02/27/15	10/07/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/07/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/07/15
	Date application submitted	05/15/15	10/07/15
1. Pre-Recelpt	Method of submission	CARS	10/07/15
	Within receipt period	YES	10/07/15
	Appeal to submit application after CARS closed	N/A	10/07/15
	Appeal for late application submission accepted	N/A	10/07/15
	Administrative review notification	N/A	10/07/15
	Donation(s) made to CPRIT/foundation	NO	10/07/15
	Assigned to primary reviewers	07/23/15	10/07/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/07/15
and Assignment	Primary Reviewer 1 COI signed	06/23/15	10/07/15
	Primary Reviewer 2 COI signed	06/23/15	10/07/15
	Primary Reviewer 3 COI signed	07/14/15	10/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/07/15
	Primary Reviewer 1 critique submitted	08/11/15	10/07/15
	Primary Reviewer 2 critique submitted	08/03/15	10/07/15
	Primary Reviewer 3 critique submitted	08/11/15	10/07/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/07/15
Evaluation	COI indicated by non-primary reviewer	NONE	10/07/15
Leandation	Preliminary Evaluation score summary sent to Chair	08/17/15	10/07/15
	Recommended for full review	YES	10/07/15
	Applicant notified of outcome	09/01/15	10/07/15
		08/25/15	10/07/15
	Assigned to primary reviewers Primary Reviewer 1 COI signed	06/23/15	10/07/15
		08/26/15	10/07/15
	Primary Reviewer 2 COI signed	07/14/15	10/07/15
	Primary Reviewer 3 COI signed	08/27/15	10/07/15
	Primary (Advocate) Reviewer 4 COI signed		
	Primary Reviewer 1 critique submitted	09/28/15	10/07/15
	Primary Reviewer 2 critique submitted	09/19/15	10/07/15
4. Peer Review	Primary Reviewer 3 critique submitted	09/22/15	10/07/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/13/15	10/07/15
	COI indicated by non-primary reviewer	NONE	10/13/15
	COI recused from participation	N/A	10/13/15
	Discussed at Peer Review Meeting	YES	10/07/15
	Peer Review Meeting	09/29/15	10/07/15
	Post review statements signed	10/12/15	10/13/15
	Third Party Observer Report	10/07/15	10/14/15
	Score report delivered to CSO	10/19/15	10/23/15
	Recommended for SRC Review	YES	10/07/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
6. PIC Review	COI recused from participation	M. Kripke	11/03/15
DITTE REVIEW	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160440 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Basic Cancer Research Panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas	
County of Travis	
SWORN to and SUBSCRIBED before methe form day of November by WAYNE R. ROBERTS.	ne, the undersigned authority, on, 2015,
SAM	
Sandra Reyes Notary Public, State of Texas	
	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2016 CYCLE 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160440

APPLICATION TITLE

Targeting the Undruggable: A First-in-Class Inhibitor of the

APPLICATION TITLE
HIF-2 Transcription Factor
APPLICANT NAME
Brugarolas, James

ORGANIZATION The University of Texas Southwestern Medical Center

PANEL NAME 16.1 Basic Cancer Research-2 (16.1 BCR-2)

Category	Compliance Regulrement	information	Attestation Dat
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
	Date application submitted	05/19/15	10/09/15
L. Pre-Receipt	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	06/18/15	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	07/20/15	10/09/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
and Assignment	Primary Reviewer 1 COI signed	06/19/15	10/09/15
	Primary Reviewer 2 COI signed	07/08/15	10/09/15
	Primary Reviewer 3 COI signed	07/14/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	08/05/15	10/09/15
	Primary Reviewer 2 critique submitted	08/08/15	10/09/15
	Primary Reviewer 3 critique submitted	08/12/15	10/09/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
Evaluation	COI indicated by non-primary reviewer	NONE	10/09/15
	Preliminary Evaluation score summary sent to Chair	08/12/15	10/09/15
	Recommended for full review	YES	10/09/15
	Applicant notified of outcome	09/01/15	10/09/15
	Assigned to primary reviewers	08/21/15	10/09/15
		07/08/15	10/09/15
	Primary Reviewer 1 COI signed	06/19/15	10/09/15
	Primary Reviewer 2 COI signed	09/10/15	10/09/15
	Primary Reviewer 3 COI signed	08/06/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	09/22/15	10/09/15
	Primary Reviewer 1 critique submitted	09/22/13	10/09/15
	Primary Reviewer 2 critique submitted	09/30/15	10/09/15
4. Peer Review	Primary Reviewer 3 critique submitted	09/12/15	10/09/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	NONE	
	COI indicated by non-primary reviewer		10/09/15
	COI recused from participation	N/A	10/09/15
	Discussed at Peer Review Meeting	YES A DIOT IN F	10/09/15
	Peer Review Meeting	10/05/15	10/09/15
	Post review statements signed	10/11/15	10/14/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/09/15
	COI Indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
5. PIC Review	COI recused from participation	M. Kripke	11/03/15
o. FIC NEVIEW	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME OF NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160451 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

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- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
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- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas	
County of Travis	
1 GYIDGGDIDED 1 C	1 1 1 1 1 1 1
SWORN to and SUBSCRIBED before me, the	
the 5th day of November	, 2015,
by WAYNE R. ROBERTS.	
Sandra Reyes Notary Public, State of Texas	_
	-
	SANDRA J. REVES
	Notary Public, State of Texas My Commission Expires
	SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160451

APPLICATION TITLE Protein Truncation Mutations in WIP1: Effects on Cancer

APPLICATION TITLE
and Hematopoiesis

APPLICANT NAME
Donehower, Lawrence
ORGANIZATION
Baylor College of Medicine

PANEL NAME 16.1 Basic Cancer Research-2 (16.1 BCR-2)

Integory.	Compiliance Requirement	Information	Attestation Dat
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
	Date application submitted	05/19/15	10/09/15
. Pre-Receipt	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	07/20/15	10/09/15
. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
nd Assignment	Primary Reviewer 1 COI signed	06/19/15	10/09/15
	Primary Reviewer 2 COI signed	06/20/15	10/09/15
	Primary Reviewer 3 COI signed	06/25/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	08/05/15	10/09/15
	Primary Reviewer 2 critique submitted	08/09/15	10/09/15
	Primary Reviewer 3 critique submitted	07/27/15	10/09/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
Evaluation	COI indicated by non-primary reviewer	NONE	10/09/15
	Preliminary Evaluation score summary sent to Chair	08/12/15	10/09/15
	Recommended for full review	YES	10/09/15
	Applicant notified of outcome	09/01/15	10/09/15
	Assigned to primary reviewers	08/21/15	10/09/15
	Primary Reviewer 1 COI signed	06/19/15	10/09/15
	Primary Reviewer 2 COI signed	06/20/15	10/09/15
	Primary Reviewer 3 COI signed	06/25/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	08/27/15	10/09/15
	Primary Reviewer 1 critique submitted	09/28/15	10/09/15
	Primary Reviewer 2 critique submitted	10/01/15	10/09/15
	Primary Reviewer 3 critique submitted	09/27/15	10/09/15
4. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	09/28/15	10/09/15
Meeting	COI indicated by non-primary reviewer	NONE	10/09/15
	COI recused from participation	N/A	10/09/15
	Discussed at Peer Review Meeting	YES	10/09/15
	Peer Review Meeting	10/05/15	10/09/15
	Post review statements signed	10/11/15	10/14/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/09/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
RECOMMENDATION	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation	M. Kripke	11/03/15
6. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME OF NONE	
		YES/NO or N/A	
	COI recused from participation	YES/NO OF N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	11/18/15	-
Committee Approval	Presented to CPRIT Oversight Committee	YES/NO	
	Award approved by Oversight Committee	VES/NO	
	Authority to advance funds requested	YES/NO	



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160460 Individual Investigator Research Awards for Prevention and Early Detection

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Prevention and Early Detection* Request for Applications (RFA). CPRIT received 45 applications for this RFA, including 1 that was later withdrawn. This application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on

the 5th day of November

, 2015,

by WAYNE R. ROBERTS.

Sandra Reyes

Notary Public, State of Texas

SANDRA J. REYES
Notary Public, State of Texas
My Commission Expires
SEPTEMBER 30, 2017

Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2016 CYCLE PROGRAM Research

Individual Investigator Research Awards for Prevention and AWARD MECHANISM

Early Detection (IIRAP) RP160460

APPLICATION ID

High Resolution Imaging for Early and Better Detection of APPLICATION TITLE

Bladder Cancer

APPLICANT NAME Richards-Kortum, Rebecca

ORGANIZATION Rice University

16.1 Imaging Technology and Informatics (16.1 $\mid T \mid$) PANEL NAME

Category	Compliance Regulrement	information	Attestation Da
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
	Date application submitted	05/20/15	10/09/15
Pre-Receipt	Method of submission	02/27/15 03/20/15 03/20/15 05/20/15 05/20/15 05/20/15 05/20/15 CARS YES N/A	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	N/A	10/09/15
. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
ind Assignment	Primary Reviewer 1 COI signed	N/A	10/09/15
ŭ	Primary Reviewer 2 COI signed		10/09/15
	Primary Reviewer 3 COI signed		10/09/15
	Primary (Advocate) Reviewer 4 COI signed		10/09/15
	Primary Reviewer 1 critique submitted		10/09/15
	Primary Reviewer 2 critique submitted		10/09/15
	Primary Reviewer 3 critique submitted		10/09/15
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted		10/09/15
valuation	COI indicated by non-primary reviewer		10/09/15
valuation	Preliminary Evaluation score summary sent to Chair		10/09/15
	Recommended for full review		10/09/15
	Applicant notified of outcome		10/09/15
	Assigned to primary reviewers		10/09/15
			10/09/15
	Primary Reviewer 1 COI signed		10/09/15
	Primary Reviewer 2 COI signed		10/09/15
	Primary Reviewer 3 COI signed		10/09/15
	Primary (Advocate) Reviewer 4 COI signed		10/09/15
	Primary Reviewer 1 critique submitted		_
	Primary Reviewer 2 critique submitted		10/09/15
. Peer Review	Primary Reviewer 3 critique submitted		10/09/15
Vieeting	Primary (Advocate) Reviewer 4 critique submitted		10/09/15
	COI indicated by non-primary reviewer	NONE	10/09/15
	COI recused from participation		10/09/15
	Discussed at Peer Review Meeting		10/09/15
	Peer Review Meeting		10/09/15
	Post review statements signed		10/09/15
	Third Party Observer Report	_	10/14/15
	Score report delivered to CSO		10/23/15
			10/09/15
	COI indicated by SRC member		10/28/15
	COI recused from participation		10/28/15
. Final SRC	SRC Meeting		10/28/15
Recommendation	Third Party Observer Report		10/28/15
	Recommended for grant award		10/28/15
	SRC Chair Notification to PIC and OC		10/28/15
	COI indicated by PIC member	NONE	11/03/15
6. PIC Review	COI recused from participation	M. Kripke	11/03/15
. FIC VEALERA	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
7. Oversight	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160462 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Basic Cancer Research Panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 5th day of November, 2015, by WAYNE R. ROBERTS.

Sandra Reyes
Notary Public, State of Texas

SANDRA J. REYES
Notary Public, State of Texas
My Commission Expires
SEPTEMBER 30, 2017

Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2016 CYCLE 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160462

APPLICATION TITLE Systematic Identification of Small Molecule Inhibitors that Manipulate Telomerase Activities

APPLICANT NAME Songyang, Zhou

ORGANIZATION Baylor College of Medicine

PANEL NAME 16_1 Basic Cancer Research-2 (16.1 BCR-2)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
1. Pre-Recelpt	Date application submitted	05/15/15	10/09/15
	Method of submission	CARS	10/09/15
	Within receipt period	02/27/15 03/20/15 05/20/15 05/20/15 05/15/15 CARS VES N/A N/A N/A N/A N/A NO 07/20/15 06/30/15 06/26/15 07/03/15 06/26/15 07/03/15 08/04/15 08/04/15 08/09/15 N/A NONE 08/12/15 08/21/15 06/26/15 06/26/15 06/26/15 06/26/15 06/26/15 06/26/15 06/26/15 06/26/15 06/26/15 06/26/15 06/26/15 06/26/15 06/26/15 06/20/15 08/27/15 09/21/15 09/28/15 10/01/15 09/28/15 10/01/15 09/28/15 10/01/15 09/28/15 10/01/15 10/13/15 10/13/15 10/13/15 10/13/15 10/13/15 10/23/15 10/27/15 VES NONE N/A N/A 10/23/15 10/27/15 VES 10/26/15 NONE N/A NKripke 11/03/15 VES DATE NAME OR NONE	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	07/20/15	10/09/15
2. Recelpt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
and Assignment	Primary Reviewer 1 COI signed	06/26/15	10/09/15
	Primary Reviewer 2 COI signed	07/03/15	10/09/15
	Primary Reviewer 3 COI signed	06/20/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	07/27/15	10/09/15
	Primary Reviewer 2 critique submitted	08/04/15	10/09/15
	Primary Reviewer 3 critique submitted	08/09/15	10/09/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	05/20/15 05/15/15 CARS YES N/A N/A N/A N/A NO 07/20/15 06/30/15 06/30/15 06/26/15 07/03/15 06/20/15 N/A 07/27/15 08/04/15 08/09/15 N/A NONE 08/12/15 06/20/15 06/20/15 06/20/15 N/A NONE 08/12/15 06/20/15 06/20/15 06/20/15 06/20/15 06/20/15 06/20/15 06/20/15 06/20/15 06/20/15 06/20/15 06/20/15 06/20/15 06/20/15 06/20/15 06/20/15 06/20/15 09/21/15 09/21/15 09/21/15 09/28/15 10/01/15 09/28/15 10/01/15 09/28/15 10/01/15 09/28/15 10/01/15 09/28/15 10/01/15 09/28/15 10/01/15 09/28/15 NONE N/A YES 10/05/15 10/11/15 10/13/15 10/19/15 YES NONE N/A 10/23/15 NONE N/A 10/23/15 10/27/15 YES 10/26/15 NONE M. Kripke 11/03/15 YES DATE	10/09/15
Evaluation	COI indicated by non-primary reviewer	NONE	10/09/15
	Preliminary Evaluation score summary sent to Chair	08/12/15	10/09/15
	Recommended for full review	YES	10/09/15
	Applicant notified of outcome	09/01/15	10/09/15
	Assigned to primary reviewers	08/21/15	10/09/15
	Primary Reviewer 1 COI signed	06/26/15	10/09/15
	Primary Reviewer 2 COI signed	06/19/15	10/09/15
	Primary Reviewer 3 COI signed	06/20/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	08/27/15	10/09/15
	Primary Reviewer 1 critique submitted	09/21/15	10/09/15
	Primary Reviewer 2 critique submitted	09/28/15	10/09/15
	Primary Reviewer 3 critique submitted		10/09/15
4. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	09/28/15	10/09/15
Meeting	COI indicated by non-primary reviewer	NONE	10/09/15
	COI recused from participation	10/01/15 09/28/15 NONE N/A	10/09/15
	Discussed at Peer Review Meeting	YES	10/09/15
	Peer Review Meeting	10/05/15	10/09/15
	Post review statements signed	10/11/15	10/14/15
	Third Party Observer Report		10/14/15
	Score report delivered to CSO		10/22/15
	Recommended for SRC Review		10/09/15
	COI Indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	YES N/A N/A N/A N/A N/A N/A NO 07/20/15 06/30/15 06/26/15 07/03/15 06/26/15 07/03/15 06/20/15 N/A 07/27/15 08/04/15 08/09/15 N/A NONE 08/12/15 09/01/15 08/21/15 06/26/15 06/20/15 08/21/15 06/26/15 06/20/15 08/27/15 09/28/15 10/01/15 09/28/15 10/01/15 09/28/15 10/01/15 10/11/15 10/13/15 10/13/15 10/13/15 10/13/15 10/13/15 10/27/15 YES NONE N/A 10/23/15 10/27/15 YES 10/26/15 NONE N/A 10/23/15 10/27/15 YES 10/26/15 NONE N/A 10/23/15 10/27/15 YES 10/26/15 NONE M. Kripke 11/03/15 YES DATE	10/27/15
Recommendation	Third Party Observer Report		10/28/15
	Recommended for grant award		10/27/15
	SRC Chair Notification to PIC and OC	_	10/28/15
	COI indicated by PIC member		11/03/15
	COI recused from participation		11/03/15
6. PIC Review	PIC review meeting		11/03/15
	Recommended for grant award		11/03/15
7 Oueminh	CEO Notification to Oversight Committee		35/5-/55
	COI indicated by Oversight Committee member		
	COI recused from participation		
7. Oversight	Donation(s) made to CPRIT/foundation Presented to CPRIT Oversight Committee		
Committee Approval			
committee Approval	Award approved by Oversight Committee Authority to advance funds requested		
	TAUTHORITY TO ADVANCE TURIOS FEDURATED	ITES/INU	



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160471 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Cancer Biology panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas	
County of Travis	
SWORN to and SUBSCRIBED before me, the _5** day of November	ne undersigned authority, on, 2015,
by WAYNE R. ROBERTS.	
Sandra Reyes Notary Public, State of Texas	
	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160471

APPLICATION TITLE Identifying New Epigenetic Vulnerabilities in Pancreatic

Cancer

APPLICANT NAME Draetta, Giulio

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME 16.1 Cancer Biology (16.1 CB)

ategory	Compliance Requirement	Informition	Attostation De
	RFA published in Texas Register	02/27/15	10/12/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/12/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/12/15
	Date application submitted	02/27/15	10/12/15
. Pre-Receipt	Method of submission	CARS	10/12/15
	Within receipt period	YES	10/12/15
	Appeal to submit application after CARS closed	N/A	10/12/15
	Appeal for late application submission accepted		10/12/15
	Administrative review notification		10/12/15
	Donation(s) made to CPRIT/foundation		10/12/15
	Assigned to primary reviewers	07/20/15	10/12/15
. Receipt, Referral,	Applicant notified of review panel assignment	_	10/12/15
nd Assignment	Primary Reviewer 1 COI signed		10/12/15
na rossbinnent	Primary Reviewer 2 COI signed		10/12/15
	Primary Reviewer 3 COI signed		10/12/15
	Primary (Advocate) Reviewer 4 COI signed	_	10/12/15
	Primary (Advocate) Reviewer 4 Col signed Primary Reviewer 1 critique submitted		10/12/15
	Primary Reviewer 2 critique submitted		10/12/15
			10/12/15
	Primary Reviewer 3 critique submitted Primary (Advocate) Reviewer 4 critique submitted		10/12/15
. Preliminary			10/12/15
valuation	COI indicated by non-primary reviewer	_	10/12/15
	Preliminary Evaluation score summary sent to Chair	_	10/12/15
	Recommended for full review		10/12/15
	Applicant notified of outcome		10/12/15
	Assigned to primary reviewers		
	Primary Reviewer 1 COI signed		10/12/15
	Primary Reviewer 2 COI signed		10/12/15
	Primary Reviewer 3 COI signed		10/12/15
	Primary (Advocate) Reviewer 4 COI signed	_	10/12/15
	Primary Reviewer 1 critique submitted	_	10/12/15
	Primary Reviewer 2 critique submitted		10/12/15
I. Peer Review	Primary Reviewer 3 critique submitted		10/12/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	10/01/15 09/06/15	10/12/15
	COI indicated by non-primary reviewer		10/12/15
	COI recused from participation	_	10/12/15
	Discussed at Peer Review Meeting		10/12/15
	Peer Review Meeting		10/12/15
	Post review statements signed		10/22/15
	Third Party Observer Report		10/14/15
	Score report delivered to CSO		10/22/15
Recommended for SRC Review	Recommended for SRC Review		10/12/15
	COI indicated by SRC member		10/27/15
	COI recused from participation		10/27/15
5. Final SRC	SRC Meeting		10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation	M Kripke	11/03/15
5. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
7. Oversight	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee		
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	-



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160482 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Clinical and Translational Cancer Research and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

County of Travis SWORN to and SUBSCRIBED before me,	the undersigned authority on
the 5th day of November	2015,
by WAYNE R. ROBERTS.	
Sandra Reyes Notary Public, State of Texas	
Notary 1 done, State of Texas	
	SANDRA J. REYES Notary Public, State of Texas My Commission Expires SEPTEMBER 30, 2017
	Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2016 CYCLE 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160482

APPLICATION TITLE Nanoparticle Targeted STAT3 Immune Expression

APPLICANT NAME Heimberger, Amy

ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME 16.1 Clinical / Translational Cancer Research (16.1 C/TCR)

Category	Compliance Regultement	Information	Attestation Dat
	RFA published in Texas Register	02/27/15	10/07/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/07/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/07/15
	Date application submitted	05/18/15	10/07/15
L. Pre-Receipt	Method of submission	CARS	10/07/15
	Within receipt period	YES	10/07/15
	Appeal to submit application after CARS closed	N/A	10/07/15
	Appeal for late application submission accepted	N/A	10/07/15
	Administrative review notification	N/A	10/07/15
	Donation(s) made to CPRIT/foundation	NO	10/07/15
	Assigned to primary reviewers	07/23/15	10/07/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/07/15
and Assignment			10/07/15
and Assignment	Primary Reviewer 1 COI signed	06/25/15	
	Primary Reviewer 2 COI signed	06/19/15	10/07/15
	Primary Reviewer 3 COI signed	06/25/15	10/07/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/07/15
	Primary Reviewer 1 critique submitted	07/24/15	10/07/15
	Primary Reviewer 2 critique submitted	08/11/15	10/07/15
	Primary Reviewer 3 critique submitted	08/13/15	10/07/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/07/15
Evaluation	COI indicated by non-primary reviewer	Engelhard, Victor	10/07/15
	Preliminary Evaluation score summary sent to Chair	08/17/15	10/07/15
	Recommended for full review	YES	10/07/15
	Applicant notified of outcome	09/01/15	10/07/15
	Assigned to primary reviewers	08/25/15	10/07/15
	Primary Reviewer 1 COI signed	06/25/15	10/07/15
	Primary Reviewer 2 COI signed	06/19/15	10/07/15
	Primary Reviewer 3 COI signed	06/25/15	10/07/15
	Primary (Advocate) Reviewer 4 COI signed	08/27/15	10/07/15
	Primary Reviewer 1 critique submitted	09/04/15	10/07/15
	Primary Reviewer 2 critique submitted	09/15/15	10/07/15
I. Peer Review	Primary Reviewer 3 critique submitted	09/26/15	10/07/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/13/15	10/07/15
	COI indicated by non-primary reviewer	Engelhard, Victor	10/13/15
	COI recused from participation	YES	10/13/15
	Discussed at Peer Review Meeting	YES	10/07/15
	Peer Review Meeting	09/29/15	10/07/15
	Post review statements signed	10/12/15	10/13/15
	Third Party Observer Report	10/07/15	10/14/15
	Score report delivered to CSO	10/19/15	10/23/15
	Recommended for SRC Review	YES	10/07/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
i. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
. PIC Review	COI recused from participation	M Kripke 11/03/15	11/03/15
	PIC review meeting		
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	4
	COI recused from participation	YES/NO or N/A	
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160487 Individual Investigator Research Awards for Cancer in Children and Adolescents

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Cancer in Children and Adolescents* Request for Applications (RFA). CPRIT received 45 applications for this RFA, including 1 that was later withdrawn. This application was assigned to the Basic Cancer Research Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on

the 5th day of November

, 2015,

by WAYNE R. ROBERTS.

Sandra Reyes

Notary Public, State of Texas

SANDRA J. REYES
Notary Public, State of Texas
My Commission Expires
SEPTEMBER 30, 2017

Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

CYCLE

1

Research

PROGRAM AWARD MECHANISM Individual Investigator Research Awards for Cancer in Children and

APPLICATION ID

Adolescents (IIRACCA) RP160487

APPLICATION TITLE

Cytokine Signaling in Ewing Sarcoma

APPLICANT NAME

Shiio, Yuzuru

ORGANIZATION

The University of Texas Health Science Center at San Antonio

PANEL NAME

16.1 Basic Cancer Research-1 (16.1 BCR-1)

Category	Compliance Requirement	information	Attestation flat
	RFA published in Texas Register	02/27/15	10/11/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/11/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/11/15
	Date application submitted	05/20/15	10/11/15
L. Pre-Receipt	Method of submission	CARS	10/11/15
	Within receipt period	YES	10/11/15
	Appeal to submit application after CARS closed	N/A	10/11/15
	Appeal for late application submission accepted	N/A	10/11/15
	Administrative review notification	N/A	10/11/15
	Donation(s) made to CPRIT/foundation	NO	10/11/15
	Assigned to primary reviewers	N/A	10/11/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/11/15
and Assignment	Primary Reviewer 1 COI signed	N/A	10/11/15
J	Primary Reviewer 2 COI signed	N/A	10/11/15
	Primary Reviewer 3 COI signed	N/A	10/11/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/11/15
	Primary Reviewer 1 critique submitted	N/A	10/11/15
	Primary Reviewer 2 critique submitted	N/A	10/11/15
	Primary Reviewer 3 critique submitted	N/A	10/11/15
2 Parlimina.		N/A	10/11/15
3. Preliminary Evaluation	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/11/15
Evaluation	COI indicated by non-primary reviewer	N/A	10/11/15
	Preliminary Evaluation score summary sent to Chair		
	Recommended for full review	N/A	10/11/15
	Applicant notified of outcome	N/A	10/11/15
	Assigned to primary reviewers	08/11/15	10/11/15
	Primary Reviewer 1 COI signed	07/02/15	10/11/15
	Primary Reviewer 2 COI signed	06/24/15	10/11/15
	Primary Reviewer 3 COI signed	06/18/15	10/11/15
	Primary (Advocate) Reviewer 4 COI signed	06/15/15	10/11/15
	Primary Reviewer 1 critique submitted	09/02/15	10/11/15
	Primary Reviewer 2 critique submitted	09/28/15	10/11/15
4. Peer Review	Primary Reviewer 3 critique submitted	10/05/15	10/11/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/06/15	10/11/15
Ü	COI indicated by non-primary reviewer	NONE	10/11/15
	COI recused from participation	N/A	10/11/15
	Discussed at Peer Review Meeting	YES	10/11/15
	Peer Review Meeting	10/06/15	10/11/15
	Post review statements signed	10/12/15	10/14/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/11/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
DIC Davison	COI recused from participation	M Kripke	11/03/15
5. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160493 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Cancer Biology panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

2016 CYCLE PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID

 ${\it Characterization\ and\ Pharmacological\ Targeting\ of\ the}$ APPLICATION TITLE

Oncogenic Activity of Jumonji Enzymes

APPLICANT NAME Martinez, Elisabeth

The University of Texas Southwestern Medical Center ORGANIZATION

PANEL NAME 16.1 Cancer Biology (16.1 CB)

Category	Compliance Regularment	Information	Attestation Dat
	RFA published in Texas Register	02/27/15	10/12/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/12/15
1. Pre-Receipt	CPRIT Application Receipt System (CARS) closed	05/20/15	10/12/15
	Date application submitted	05/19/15	10/12/15
	Method of submission	CARS	10/12/15
	Within receipt period	YES	10/12/15
	Appeal to submit application after CARS closed	N/A	10/12/15
	Appeal for late application submission accepted	N/A	10/12/15
	Administrative review notification	N/A	10/12/15
	Donation(s) made to CPRIT/foundation	NO	10/12/15
	Assigned to primary reviewers	07/20/15	10/12/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/12/15
and Assignment	Primary Reviewer 1 COI signed	06/24/15	10/12/15
	Primary Reviewer 2 COI signed	07/03/15	10/12/15
	Primary Reviewer 3 COI signed	06/18/15	10/12/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/12/15
	Primary Reviewer 1 critique submitted	08/06/15	10/12/15
	Primary Reviewer 2 critique submitted	08/06/15	10/12/15
	Primary Reviewer 3 critique submitted	07/27/15	10/12/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/12/15
evaluation	COI indicated by non-primary reviewer	NONE	10/12/15
	Preliminary Evaluation score summary sent to Chair	08/10/15	10/12/15
	Recommended for full review	YES	10/12/15
	Applicant notified of outcome	09/01/15	10/12/15
	Assigned to primary reviewers	08/18/15	10/12/15
	Primary Reviewer 1 COI signed	06/18/15	10/12/15
	Primary Reviewer 2 COI signed	06/24/15	10/12/15
	Primary Reviewer 3 COI signed	07/03/15	10/12/15
	Primary (Advocate) Reviewer 4 COI signed	06/19/15	10/12/15
	Primary (Advocate) Neviewer 4 corriginal	09/15/15	10/12/15
	Primary Reviewer 2 critique submitted	10/01/15	10/12/15
	Primary Reviewer 3 critique submitted	09/30/15	10/12/15
4. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	09/18/15	10/12/15
Meeting	COI indicated by non-primary reviewer	NONE	10/12/15
	COI recused from participation	N/A	10/12/15
	Discussed at Peer Review Meeting	YES	10/12/15
		10/07/15	10/12/15
	Peer Review Meeting	10/15/15	10/22/15
	Post review statements signed Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES YES	10/12/15
		NONE	10/27/15
	COI indicated by SRC member	N/A	10/27/15
et tone	COI recused from participation	10/23/15	10/27/15
5. Final SRC	SRC Meeting	10/23/13	10/28/15
Recommendation	Third Party Observer Report	YES YES	10/27/15
	Recommended for grant award		10/28/15
	SRC Chair Notification to PIC and OC	10/26/15	
	COI indicated by PIC member	NONE	11/03/15
5. PIC Review	COI recused from participation	M. Kripke 11/03/15	11/03/15
	PIC review meeting		11/03/15
	Recommended for grant award	YES	11/05/15
	CEO Notification to Oversight Committee	DATE OF NOME	
	COI indicated by Oversight Committee member	NAME OF NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160497 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

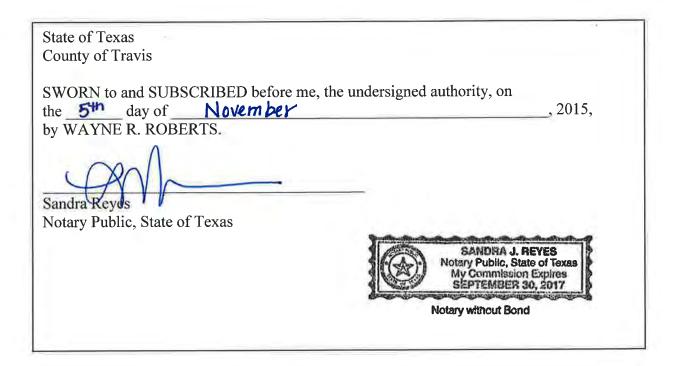
In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160497

APPLICANT NAME

APPLICATION TITLE

Amplified Gold Nanoparticle-Mediated Radiosensitization

of Tumors Krishnan, Sunil

 ORGANIZATION
 The University of Texas M. D. Anderson Cancer Center

 PANEL NAME
 16.1 Imaging Technology and Informatics (16.1 ITI)

Category	Compliance Requirement	Information	Attestation 0
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
	Date application submitted	05/18/15	10/09/15
L. Pre-Receipt	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	07/22/15	10/09/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
and Assignment	Primary Reviewer 1 COI signed	07/04/15	10/09/15
	Primary Reviewer 2 COI signed	06/30/15	10/09/15
	Primary Reviewer 3 COI signed	06/23/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	08/07/15	10/09/15
	Primary Reviewer 2 critique submitted	08/05/15	10/09/15
	Primary Reviewer 3 critique submitted	07/30/15	10/09/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
Evaluation	COI indicated by non-primary reviewer	Berbeco, Ross	10/09/15
	Preliminary Evaluation score summary sent to Chair	08/11/15	10/09/15
	Recommended for full review	YES	10/09/15
	Applicant notified of outcome	09/01/15	10/09/15
	Assigned to primary reviewers	08/17/15	10/09/15
		07/04/15	10/09/15
	Primary Reviewer 1 COI signed	06/30/15	
	Primary Reviewer 2 COI signed		10/09/15
	Primary Reviewer 3 COI signed	06/23/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	07/09/15	10/09/15
	Primary Reviewer 1 critique submitted		
	Primary Reviewer 2 critique submitted	09/21/15	10/09/15
I. Peer Review	Primary Reviewer 3 critique submitted	09/19/15	10/09/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/05/15	10/09/15
	COI indicated by non-primary reviewer	Berbeco, Ross	10/09/15
	COI recused from participation	YES	10/09/15
	Discussed at Peer Review Meeting	YES	10/09/15
	Peer Review Meeting	10/01/15	10/09/15
	Post review statements signed	10/08/15	10/09/15
	Third Party Observer Report	10/07/15	10/14/15
	Score report delivered to CSO	10/19/15	10/23/15
	Recommended for SRC Review	YES	10/09/15
	COI indicated by SRC member	NONE	10/28/15
	COI recused from participation	N/A	10/28/15
5. Final SRC	SRC Meeting	10/23/15	10/28/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/28/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
i. PIC Review	COI recused from participation	M. Kripke	11/03/15
. FIC KENEW	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160501 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Basic Cancer Research Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on the 5th day of November . 2015, by WAYNE R. ROBERTS.

Sandra Reyes
Notary Public, State of Texas

Notary Public, State of Texas

SANDRA J. REYES
Notary Public, State of Texas
My Commission Expires
SEPTEMBER 30, 2017
Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

2016 CYCLE PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160501

APPLICATION TITLE De-Orphanizing TLX: Implications for Glioblastomas

APPLICANT NAME Webb, Paul

The Methodist Hospital Research Institute ORGANIZATION PANEL NAME 16,1 Basic Cancer Research-1 (16.1 BCR-1)

Citegory	Compliance Requirement	Information	Attestation Da
	RFA published in Texas Register	02/27/15	10/11/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/11/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/11/15
	Date application submitted	05/18/15	10/11/15
. Pre-Receipt	Method of submission	CARS	10/11/15
	Within receipt period	YES	10/11/15
	Appeal to submit application after CARS closed	N/A	10/11/15
	Appeal for late application submission accepted	N/A	10/11/15
	Administrative review notification	N/A	10/11/15
	Donation(s) made to CPRIT/foundation	NO	10/11/15
	Assigned to primary reviewers	07/17/15	10/11/15
. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/11/15
and Assignment	Primary Reviewer 1 COI signed	06/26/15	10/11/15
	Primary Reviewer 2 COI signed	06/18/15	10/11/15
	Primary Reviewer 3 COI signed	07/03/15	10/11/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/11/15
	Primary Reviewer 1 critique submitted	08/05/15	10/11/15
	Primary Reviewer 2 critique submitted	08/06/15	10/11/15
	Primary Reviewer 3 critique submitted	08/05/15	10/11/15
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/11/15
valuation	COI indicated by non-primary reviewer	NONE	10/11/15
valuation	Preliminary Evaluation score summary sent to Chair	08/06/15	10/11/15
		YES	10/11/15
	Recommended for full review		10/11/15
	Applicant notified of outcome	09/01/15 08/11/15	10/11/15
	Assigned to primary reviewers		
	Primary Reviewer 1 COI signed	06/26/15	10/11/15
	Primary Reviewer 2 COI signed	06/18/15	10/11/15
	Primary Reviewer 3 COI signed	07/03/15	10/11/15
	Primary (Advocate) Reviewer 4 COI signed	06/18/15	10/11/15
	Primary Reviewer 1 critique submitted	09/28/15	10/11/15
	Primary Reviewer 2 critique submitted	10/05/15	10/11/15
4. Peer Review	Primary Reviewer 3 critique submitted	09/30/15	10/11/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/21/15	10/11/15
, and the second	COI indicated by non-primary reviewer	NONE	10/11/15
	COI recused from participation	N/A	10/11/15
	Discussed at Peer Review Meeting	YES	10/11/15
	Peer Review Meeting	10/06/15	10/11/15
	Post review statements signed	10/12/15	10/14/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/11/15
	COI Indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation	M. Kripke	11/03/15
5. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME OF NONE	
	COI recused from participation	YES/NO of N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Transcript to detailed railed respection	YES/NO	

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160512 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Clinical and Translational Cancer Research and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

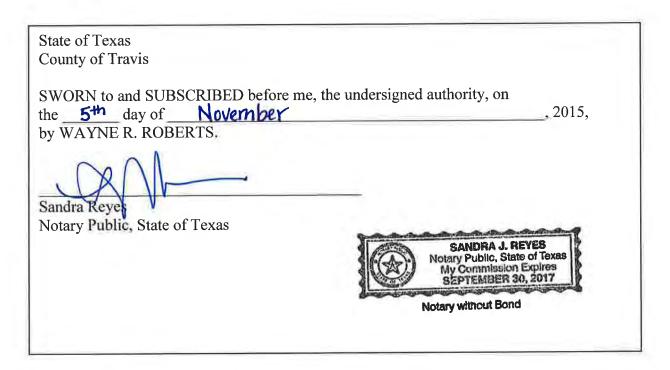
In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2016 CYCLE 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160512

APPLICATION TITLE Integrin-mediated IL-18 Signaling in the Prevention and Treatment of Inflammation-Associated Colorectal Cancer

APPLICANT NAME Dube, Peter

ORGANIZATION The University of Texas Health Science Center at San Antonio

PANEL NAME 16.1 Clinical / Translational Cancer Research (16.1 C/TCR)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
Des Dessies	Date application submitted	05/19/15	10/09/15
l. Pre-Receipt	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	07/23/15	10/09/15
. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
and Assignment	Primary Reviewer 1 COI signed	06/23/15	10/09/15
	Primary Reviewer 2 COI signed	07/06/15	10/09/15
	Primary Reviewer 3 COI signed	06/22/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	08/09/15	10/09/15
	Primary Reviewer 2 critique submitted	08/11/15	10/09/15
	Primary Reviewer 3 critique submitted	08/07/15	10/09/15
I. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
valuation	COI indicated by non-primary reviewer	NONE	10/09/15
	Preliminary Evaluation score summary sent to Chair	08/17/15	10/09/15
	Recommended for full review	YES	10/09/15
	Applicant notified of outcome	09/01/15	10/09/15
	Assigned to primary reviewers	08/25/15	10/09/15
	Primary Reviewer 1 COI signed	08/29/15	10/09/15
	Primary Reviewer 2 COI signed	07/06/15	10/09/15
	Primary Reviewer 3 COI signed	08/26/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	07/29/15	10/09/15
	Primary (Advocate) Reviewer 4 Col signed Primary Reviewer 1 critique submitted	09/13/15	10/09/15
	Primary Reviewer 2 critique submitted	09/28/15	10/09/15
	Primary Reviewer 3 critique submitted	09/19/15	10/09/15
. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	09/14/15	10/09/15
Vleeting		NONE	10/09/15
	COI regular from participation		
	COI recused from participation	N/A YES	10/09/15
	Discussed at Peer Review Meeting	09/29/15	
	Peer Review Meeting		10/09/15
	Post review statements signed	10/12/15	10/13/15
	Third Party Observer Report	10/07/15	10/14/15
	Score report delivered to CSO	10/19/15	10/23/15
	Recommended for SRC Review	YES	10/09/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
. PIC Review	COI recused from participation	M. Kripke	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160517 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Clinical and Translational Cancer Research and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

CYCLE 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160517

APPLICATION TITLE Exosomal DNA as a Surrogate Biomarker for Early Diagnosis and

Therapeutic Stratification in Pancreatic Cancer

APPLICANT NAME Maitra, Anirban

 ORGANIZATION
 The University of Texas M. D. Anderson Cancer Center

 PANEL NAME
 16.1 Clinical / Translational Cancer Research (16.1 C/TCR)

Category	Compliance Requirement	Information	Attestation Dat
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
	Date application submitted	05/19/15	10/09/15
. Pre-Receipt	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	07/23/15	10/09/15
. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
nd Assignment	Primary Reviewer 1 COI signed	07/06/15	10/09/15
	Primary Reviewer 2 COI signed	07/06/15	10/09/15
	Primary Reviewer 3 COI signed	07/02/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	08/01/15	10/09/15
	Primary Reviewer 2 critique submitted	08/11/15	10/09/15
	Primary Reviewer 3 critique submitted	08/13/15	10/09/15
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
valuation	COI indicated by non-primary reviewer	NONE	10/09/15
	Preliminary Evaluation score summary sent to Chair	08/17/15	10/09/15
	Recommended for full review	YES	10/09/15
	Applicant notified of outcome	09/01/15	10/09/15
	Assigned to primary reviewers	08/25/15	10/09/15
	Primary Reviewer 1 COI signed	07/06/15	10/09/15
	Primary Reviewer 2 COI signed	07/06/15	10/09/15
	Primary Reviewer 3 COI signed	06/20/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	06/15/15	10/09/15
	Primary Reviewer 1 critique submitted	09/20/15	10/09/15
	Primary Reviewer 2 critique submitted	09/28/15	10/09/15
	Primary Reviewer 3 critique submitted	09/20/15	10/09/15
. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	09/17/15	10/09/15
/leeting	COI indicated by non-primary reviewer	NONE	10/09/15
	COI recused from participation	N/A	10/09/15
	Discussed at Peer Review Meeting	YES	10/09/15
		09/29/15	10/09/15
	Peer Review Meeting	10/12/15	10/13/15
	Post review statements signed		10/14/15
	Third Party Observer Report	10/07/15	-
	Score report delivered to CSO	10/19/15	10/23/15
	Recommended for SRC Review	YES	10/09/15
	COI indicated by SRC member	NONE	10/27/15
etlene	COI recused from participation	N/A	10/27/15
. Final SRC	SRC Meeting	10/23/15	10/27/15
ecommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PiC member	NONE	11/03/15
. PIC Review	COI recused from participation	M. Kripke	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/10/15	
ommittee Approvat			
ommittee Approval	Award approved by Oversight Committee Authority to advance funds requested	YES/NO YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160520 Individual Investigator Research Awards for Prevention and Early Detection

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Prevention and Early Detection* Request for Applications (RFA). CPRIT received 45 applications for this RFA, including 1 that was later withdrawn. This application was assigned to the Clinical and Translational Cancer Research and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas

County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on

the 5th day of November

, 2015,

by WAYNE R. ROBERTS.

Sandra Reves

Notary Public, State of Texas

SANDRA J. REYES
Notary Public, State of Texas
My Commission Expires
SEPTEMBER 30, 2017

Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards for Prevention and Early

APPLICATION ID RP160520

APPLICATION TITLE Effect of Chest Radiation Therapy on Cardiomyocyte Turnover

APPLICANT NAME Sadek, Hesham

 ORGANIZATION
 The University of Texas Southwestern Medical Center

 PANEL NAME
 16.1 Clinical / Translational Cancer Research (16.1 C/TCR)

Category	Compliance Regultement	Information	Attestation D
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
	Date application submitted	05/20/15	10/09/15
. Pre-Receipt	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	N/A	10/09/15
. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
nd Assignment	Primary Reviewer 1 COI signed	N/A	10/09/15
	Primary Reviewer 2 COI signed	N/A	10/09/15
	Primary Reviewer 3 COI signed	N/A	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	N/A	10/09/15
	Primary Reviewer 2 critique submitted	N/A	10/09/15
	Primary Reviewer 3 critique submitted	N/A	10/09/15
. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
valuation	COI indicated by non-primary reviewer	N/A	10/09/15
	Preliminary Evaluation score summary sent to Chair	N/A	10/09/15
	Recommended for full review	N/A	10/09/15
	Applicant notified of outcome	N/A	10/09/15
	Assigned to primary reviewers	08/25/15	10/09/15
	Primary Reviewer 1 COI signed	07/23/15	10/09/15
	Primary Reviewer 2 COI signed	07/16/15	10/09/15
	Primary Reviewer 3 COI signed	08/09/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	07/29/15	10/09/15
	Primary Reviewer 1 critique submitted	09/21/15	10/09/15
	Primary Reviewer 2 critique submitted	09/22/15	10/09/15
	Primary Reviewer 3 critique submitted	09/28/15	10/09/15
. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	09/14/15	10/09/15
/leeting	COI indicated by non-primary reviewer	NONE	10/09/15
	COI recused from participation	N/A	10/09/15
	-	YES	10/09/15
	Discussed at Peer Review Meeting	09/29/15	10/09/15
	Peer Review Meeting	10/12/15	10/13/15
	Post review statements signed	10/12/15	10/13/15
	Third Party Observer Report	10/19/15	10/23/15
	Score report delivered to CSO	YES YES	10/09/15
	Recommended for SRC Review	NONE	10/03/15
	COI indicated by SRC member	N/A	10/27/15
	COI recused from participation		10/27/15
. Final SRC	SRC Meeting	10/23/15	10/27/13
lecommendation	Third Party Observer Report	10/27/15	
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	
. PIC Review	COI recused from participation	M. Kripke	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	VES/NO or N/A	
. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160577 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Clinical and Translational Cancer Research and Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2016 CYCLE 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160577

APPLICATION TITLE A Novel Function of Itch in Controlling IL-17-Induced Inflammation in Colon Cancer

APPLICANT NAME Poojary, Venuprasad
ORGANIZATION Baylor Research Institute

PANEL NAME 16,1 Clinical / Translational Cancer Research (16.1 C/TCR)

Category	Compliance Requirement	Information	Attestation Da
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
1. Pre-Receipt	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
	Date application submitted	05/20/15	10/09/15
	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	07/23/15	10/09/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
and Assignment	Primary Reviewer 1 COI signed	06/30/15	10/09/15
	Primary Reviewer 2 COI signed	07/14/15	10/09/15
	Primary Reviewer 3 COI signed	06/30/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary (Advocate) Reviewer 4 Corsigned Primary Reviewer 1 critique submitted	08/11/15	10/09/15
	Primary Reviewer 2 critique submitted	08/11/15	10/09/15
	Primary Reviewer 3 critique submitted	08/09/15	10/09/15
n Davidson		N/A	10/09/15
3. Preliminary Evaluation	Primary (Advocate) Reviewer 4 critique submitted		
LValuation	COI indicated by non-primary reviewer	Cooney, Kathleen 08/17/15	10/09/15
	Preliminary Evaluation score summary sent to Chair	VES YES	
	Recommended for full review		10/09/15
	Applicant notified of outcome	09/01/15	10/09/15
	Assigned to primary reviewers	08/25/15	10/09/15
	Primary Reviewer 1 COI signed	06/30/15	10/09/15
	Primary Reviewer 2 COI signed	07/14/15	10/09/15
	Primary Reviewer 3 COI signed	06/30/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	07/29/15	10/09/15
	Primary Reviewer 1 critique submitted	09/21/15	10/09/15
	Primary Reviewer 2 critique submitted	09/21/15	10/09/15
4. Peer Review	Primary Reviewer 3 critique submitted	09/21/15	10/09/15
Meeting	Primary (Advocate) Reviewer 4 critique submitted	09/14/15	10/09/15
	COI indicated by non-primary reviewer	Cooney, Kathleen	10/09/15
	COI recused from participation	YES	10/09/15
	Discussed at Peer Review Meeting	YES	10/09/15
	Peer Review Meeting	09/29/15	10/09/15
	Post review statements signed	10/12/15	10/13/15
	Third Party Observer Report	10/07/15	10/14/15
	Score report delivered to CSO	10/19/15	10/23/15
	Recommended for SRC Review	YES	10/09/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
5. Final SRC	SRC Meeting	10/23/15	10/27/15
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation	M. Kripke	11/03/15
5. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	1
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
- при	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Industry to advance rains requested	120/110	

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160589 Individual Investigator Research Awards for Prevention and Early Detection

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Prevention and Early Detection* Request for Applications (RFA). CPRIT received 45 applications for this RFA, including 1 that was later withdrawn. This application was assigned to the Cancer Biology panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas

County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on

the 5th day of November . 2015, by WAYNE R. ROBERTS.

Sandra Reyes

Notary Public, State of Texas

SANDRA J. REYES
Notary Public, State of Texas
My Commission Expires
SEPTEMBER 30, 2017

Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

 FY
 2016

 CYCLE
 1

 PROGRAM
 Research

AWARD MECHANISM Individual Investigator Research Awards for Prevention

and Early Detection (IIRAP)

APPLICATION ID RP160589

APPLICATION TITLE Arylhydrocarbon Receptor Mediated Modulation of Colorectal Cancer by Microbiota Metabolites

APPLICANT NAME Chapkin, Robert
ORGANIZATION Texas AgriLife Research
PANEL NAME 16,1 Cancer Biology (16.1 CB)

Category	Compliance Requirement	Information	Attestation D
	RFA published in Texas Register	02/27/15	10/12/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/12/15
1. Pre-Receipt	CPRIT Application Receipt System (CARS) closed	05/20/15	10/12/15
	Date application submitted	05/20/15	10/12/15
	Method of submission	CARS	10/12/15
	Within receipt period	YES	10/12/15
	Appeal to submit application after CARS closed	N/A	10/12/15
	Appeal for late application submission accepted	N/A	10/12/15
	Administrative review notification	N/A	10/12/15
	Donation(s) made to CPRIT/foundation	NO	10/12/15
	Assigned to primary reviewers	N/A	10/12/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/12/15
and Assignment	Primary Reviewer 1 COI signed	N/A	10/12/15
	Primary Reviewer 2 COI signed	N/A	10/12/15
	Primary Reviewer 3 COI signed	N/A	10/12/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/12/15
	Primary Reviewer 1 critique submitted	N/A	10/12/15
	Primary Reviewer 2 critique submitted	N/A	10/12/15
	Primary Reviewer 3 critique submitted	N/A	10/12/15
s. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/12/15
valuation	COI indicated by non-primary reviewer	N/A	10/12/15
	Preliminary Evaluation score summary sent to Chair	N/A	10/12/15
	Recommended for full review	N/A	10/12/15
	Applicant notified of outcome	N/A	10/12/15
	Assigned to primary reviewers	08/18/15	10/12/15
	Primary Reviewer 1 COI signed	07/06/15	10/12/15
	Primary Reviewer 2 COI signed	07/08/15	10/12/15
	Primary Reviewer 3 COI signed	07/06/15	10/12/15
	Primary (Advocate) Reviewer 4 COI signed	08/13/15	10/12/15
	Primary Reviewer 1 critique submitted	09/28/15	10/12/15
	Primary Reviewer 2 critique submitted	09/28/15	10/12/15
	Primary Reviewer 3 critique submitted	10/01/15	10/12/15
	Primary (Advocate) Reviewer 4 critique submitted	09/14/15	10/12/15
. Peer Review	COI indicated by non-primary reviewer	Fearon, Eric	10/12/15
/leeting	COI recused from participation	YES	10/12/15
	COI indicated by non-primary reviewer	Greene, Geoffrey	10/12/15
	COI recused from participation	YES	10/12/15
	Discussed at Peer Review Meeting	YES	10/12/15
	Peer Review Meeting	10/07/15	10/12/15
	Post review statements signed	10/15/15	10/22/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/12/15
	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
. Final SRC	SRC Meeting	10/23/15	10/27/15
ecommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
	COI recused from participation	M. Kripke	11/03/15
. PIC Review	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	11/03/13
	COI indicated by Oversight Committee	NAMEGENONE	
	COI recused from participation	YES/NO or N/A	
Overeight		YES/NO OF N/A	
Oversight ommittee Approval	Procented to CPRIT Oversight Committee		
ommittee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee Authority to advance funds requested	YES/NO YES/NO	
		ETESTING	-18

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160617 Individual Investigator Research Awards

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards* Request for Applications (RFA). CPRIT received 351 applications for this RFA, including 5 that were later withdrawn. This application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two de-identified lists of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified list for the applications that did not move past the preliminary evaluation review stage in this cycle is listed as "Final Scores for Preliminary Evaluations." As explained in 25 T.A.C. § 703.6(e)(1)(C), it is the responsibility of the peer review panel chairperson to determine which grant applications move forward to full review from preliminary evaluation. The chairperson's decision is based on several factors including the preliminary evaluation scores by the assigned primary reviewers and their comments.

The de-identified list for the applications that received full review is listed as "Final Scores for Fully Reviewed Applications."

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have

also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2016 CYCLE 1

PROGRAM Research

AWARD MECHANISM Individual Investigator Research Awards (IIRA)

APPLICATION ID RP160617

APPLICATION TITLE
Optimizing Therapeutic Strategies Against Lung Cancer

using Multi-Modality Imaging

APPLICANT NAME Zhang, Li

ORGANIZATION The University of Texas at Dallas

PANEL NAME 16.1 Imaging Technology and Informatics (16.1 ITI)

Category	Compliance Requirement	Information	Attestation I
	RFA published in Texas Register	02/27/15	10/09/15
	CPRIT Application Receipt System (CARS) opened	03/20/15	10/09/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/09/15
1. Pre-Receipt	Date application submitted	05/19/15	10/09/15
i. Pre-Receipt	Method of submission	CARS	10/09/15
	Within receipt period	YES	10/09/15
	Appeal to submit application after CARS closed	N/A	10/09/15
	Appeal for late application submission accepted	N/A	10/09/15
	Administrative review notification	N/A	10/09/15
	Donation(s) made to CPRIT/foundation	NO	10/09/15
	Assigned to primary reviewers	07/22/15	10/09/15
2. Receipt, Referral,	Applicant notified of review panel assignment	06/30/15	10/09/15
and Assignment	Primary Reviewer 1 COI signed	07/06/15	10/09/15
	Primary Reviewer 2 COI signed	07/07/15	10/09/15
	Primary Reviewer 3 COI signed	07/11/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/09/15
	Primary Reviewer 1 critique submitted	07/29/15	10/09/15
	Primary Reviewer 2 critique submitted	08/05/15	10/09/15
	Primary Reviewer 3 critique submitted	08/09/15	10/09/15
3. Preliminary	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/09/15
Evaluation	COI indicated by non-primary reviewer	NONE	10/09/15
	Preliminary Evaluation score summary sent to Chair	08/11/15	10/09/15
	Recommended for full review	YES	10/09/15
	Applicant notified of outcome	09/01/15	10/09/15
	Assigned to primary reviewers	08/17/15	10/09/15
	Primary Reviewer 1 COI signed	07/06/15	10/09/15
	Primary Reviewer 2 COI signed	07/07/15	10/09/15
	Primary Reviewer 3 COI signed	07/11/15	10/09/15
	Primary (Advocate) Reviewer 4 COI signed	07/13/15	10/09/15
	Primary Reviewer 1 critique submitted	09/25/15	10/09/15
	Primary Reviewer 2 critique submitted	09/22/15	10/09/15
	Primary Reviewer 3 critique submitted	09/24/15	10/09/15
4. Peer Review	Primary (Advocate) Reviewer 4 critique submitted	09/24/15	10/09/15
Meeting	COI indicated by non-primary reviewer	NONE	10/09/15
	COI recused from participation	N/A	10/09/15
	Discussed at Peer Review Meeting	YES	10/09/15
		10/01/15	10/09/15
	Peer Review Meeting	10/08/15	10/09/15
	Post review statements signed		10/14/15
	Third Party Observer Report	10/07/15	_
	Score report delivered to CSO	10/19/15 YES	10/23/15
	Recommended for SRC Review	NONE	10/09/15
	COI indicated by SRC member		10/28/15
	COI recused from participation	N/A	10/28/15
5. Final SRC	SRC Meeting	10/23/15	
Recommendation	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/28/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
	COI indicated by PIC member	NONE	11/03/15
6. PIC Review	COI recused from participation	M. Kripke	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
7. Oversight	Donation(s) made to CPRIT/foundation	YES/NO	
Committee Approval	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	_

Dr. Kripke has an approved conflict of interest waiver on file for FY2016 regarding MD Anderson applications



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT Application RP160622 Individual Investigator Research Awards for Computational Biology

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Awards for Computational Biology* Request for Applications (RFA). CPRIT received 50 applications for this RFA. This application was assigned to the Cancer Biology panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

• A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each mechanism, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not move forward. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

Additionally, after receiving recommendations by the peer review panels, the Scientific Review Council made adjustments to the success rates of some of the peer review panels as to bring them in line with the remaining panels. This resulted in a reduction by 10 of applications recommended to the PIC.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Mr. Kirk Cole, Department of State Health Services Interim Commissioner, have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that members Will Montgomery and Amy Mitchell also have conflict of interest waivers on file for FY2016 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules. This statement is true."

Wayne R. Roberts,

CEO, Cancer Prevention and Research Institute of Texas

State of Texas

County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on November

, 2015,

by WAYNE R. ROBERTS.

day of

Notary Public, State of Texas

SANDRA J. REYES Notary Public, State of Taxas My Commission Expires SEPTEMBER 30, 2017

Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS APPLICATION PEDIGREE

FY 2016 CYCLE PROGRAM

Research

AWARD MECHANISM Individual Investigator Research Awards for Computational Biology (IIRACB)

APPLICATION ID RP160622

APPLICATION TITLE Computational Live Cell Histology

APPLICANT NAME Danuser, Gaudenz

The University of Texas Southwestern Medical Center ORGANIZATION

PANEL NAME 16,1 Cancer Biology (16.1 CB)

Category	Compliance Requirement	Information	Attestation Date
	RFA published in Texas Register	02/27/15	10/12/15
1. Pre-Receipt	CPRIT Application Receipt System (CARS) opened	03/20/15	10/12/15
	CPRIT Application Receipt System (CARS) closed	05/20/15	10/12/15
	Date application submitted	05/19/15	10/12/15
	Method of submission	CARS	10/12/15
	Within receipt period	YES	10/12/15
	Appeal to submit application after CARS closed	N/A	10/12/15
	Appeal for late application submission accepted	N/A	10/12/15
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/12/15
	Donation(s) made to CPRIT/foundation	NO	10/12/15
	Assigned to primary reviewers	N/A	10/12/15
	Applicant notified of review panel assignment	06/30/15	10/12/15
	Primary Reviewer 1 COI signed	N/A	10/12/15
	Primary Reviewer 2 COI signed	N/A	10/12/15
	Primary Reviewer 3 COI signed	N/A	10/12/15
	Primary (Advocate) Reviewer 4 COI signed	N/A	10/12/15
3. Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	10/12/15
	Primary Reviewer 2 critique submitted	N/A	10/12/15
	Primary Reviewer 3 critique submitted	N/A	10/12/15
	Primary (Advocate) Reviewer 4 critique submitted	N/A	10/12/15
	COI indicated by non-primary reviewer	N/A	10/12/15
	Preliminary Evaluation score summary sent to Chair	N/A	10/12/15
	Recommended for full review	N/A	10/12/15
	Applicant notified of outcome	N/A	10/12/15
4. Peer Review Meeting	Assigned to primary reviewers	08/18/15	10/12/15
	Primary Reviewer 1 COI signed	07/06/15	10/12/15
	Primary Reviewer 2 COI signed	07/06/15	10/12/15
	Primary Reviewer 3 COI signed	06/23/15	10/12/15
	Primary (Advocate) Reviewer 4 COI signed	06/19/15	10/12/15
	Primary Reviewer 1 critique submitted	09/30/15	10/12/15
	Primary Reviewer 2 critique submitted	09/19/15	10/12/15
	Primary Reviewer 3 critique submitted	09/26/15	10/12/15
	Primary (Advocate) Reviewer 4 critique submitted	09/18/15	10/12/15
	COI indicated by non-primary reviewer	NONE	10/12/15
	COI recused from participation	N/A	10/12/15
	Discussed at Peer Review Meeting	YES	10/12/15
	Peer Review Meeting	10/07/15	10/12/15
	Post review statements signed	10/15/15	10/22/15
	Third Party Observer Report	10/13/15	10/14/15
	Score report delivered to CSO	10/19/15	10/22/15
	Recommended for SRC Review	YES	10/12/15
5. Final SRC Recommendation	COI indicated by SRC member	NONE	10/27/15
	COI recused from participation	N/A	10/27/15
	SRC Meeting	10/23/15	10/27/15
	Third Party Observer Report	10/27/15	10/28/15
	Recommended for grant award	YES	10/27/15
	SRC Chair Notification to PIC and OC	10/26/15	10/28/15
6. PIC Review	COI Indicated by PIC member	NONE	11/03/15
	COI recused from participation	N/A	11/03/15
	PIC review meeting	11/03/15	11/03/15
	Recommended for grant award	YES	11/03/15
7. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI Indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	11/18/15	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	1
	Advance authority approved by Oversight Committee	YES/NO	